On the Road towards new R&D-based business models to sustain value creation in Big Pharmaceutical Companies: Exploring the case of Roche

Abstract.

Big pharmaceutical companies develop new business models to cope with the innovation crisis (patent loss, drying up of pipelines) and to improve their productivity in R&D and innovation. These pressures led big players to transform or reinvent their business models to sustain value creation from R&D and innovation. However, to our knowledge, there is still a lack of understanding regarding the "strategic alignment" of these organizational changes and on how they are perceived by organizational members. This assessment is important to identify both the levers and obstacles and, if necessary, to shape or reorient organizational change. In 2007, a new organization of Research and Development was implemented within Roche. The R&D is a matrix organization with five autonomous DBAs (.Disease Biology Areas). The new model is designed to ensure that Roche's steadily expanding R&D operations are suitably equipped to meet increasingly complex requirements. By simplifying and accelerating the multiple decision-making processes involved, the model would be more efficient and effective in translating research activity in each therapeutic area into clinically differentiated medicines. It also enables an improved integration of the Group's growing number of development projects. A decision was made to use Burke and Litwin's (1992) model of organizational performance and change to assess how transformational and transactional factors are perceived by key actors (managers, team leaders and team members). Data collection and analysis (secondary and primary data) and questionnaires (62 interviews) relating to these factors show that progress has been made and that some other issues still have to be improved. Besides the vision, mission and values associated with the Roche project, that have been clearly communicated and understood, significant progress has been made in the quality of the decision-making process due to the cross functional cooperation between research and early development in the matrix organization (DBA) (time, simplification, flexibility). However, this structure is perceived as being complex. There is a positive relation between improvements in communication and the positive perception of the new structure. Even if respondents think that the implementation of the Roche project takes time and effort, they also think that substantial improvements will follow. A majority of the interviewees perceived that there are too many processes within Roche. This diagnosis also pointed out issues that need to be improved, like communication between teams and departments, idea generation and implementation. This analysis led to the conclusion that change processes induced by the Roche project are characterized by stable and dynamic dimensions. Stable dimensions are transformational and oriented towards the long term. They cover the company's vision, mission, values, and strategies, while dynamic dimensions relate to the organizational structures, and, more importantly, to the "human factor" that is considered as the key success factor in creating value.

Key words : Innovation, Pharmaceutical Industry, strategic and organizational change

1- INTRODUCTION AND BACKGROUND .

Our research is situated at the interface between two main streams of literature; (i) strategic and organizational change and (ii) organizational designs for R&D and innovation.

The pharmaceutical industry is facing an “innovation crisis” characterized by the drastic decrease in productivity in its R&D and marketing of new molecules. The decrease in innovation capacity of Big Pharmaceutical companies threatens their short and long term economic performance. This crisis has been amplified and reinforced by changes in external factors (pressure of public payers, regulation authorities, development of generic drugs etc.) and/or internal factors (patent loss, drying up of the innovation pipeline, lack of R&D productivity, etc.) creating a strong pressure on big pharmaceutical companies. This situation has led them to adapt their strategy and to transform their organization to preserve their income and ability to generate and support innovations.

1.1-THE CONTEXT: STRONG EXTERNAL AND INTERNAL PRESSURES ON R&D AND INNOVATION IN BIG PHARMACEUTICAL COMPANIES

The combined pressure of ‘external factors” like price reduction and risk-averse behavior by governments and regulatory bodies play an important role in the industry putting pressure on R&D and innovation led by big pharmaceutical companies (EFPIA, 2011).

Governments of the major pharmaceutical markets, (USA and Europe, representing 75% of global sales), have adopted various strategies to control and reduce drug prices. The non reimbursement measures range from simple molecules with proven added value (as in France) to variable reimbursement programs depending on the performance of a treatment (in the UK). The theme of these programs is the cost/benefits related to price, which are proportional to the clinical and economic performance of the molecule, compared to the best current treatment rather than a placebo. The strong pressure on prices has facilitated, in parallel with the loss of many blockbuster patents, a rapid and strong penetration of generics, weakening the competitive position of all pharmaceutical companies (Drummond, 2012). The market for generic drugs nowadays represents 10% of the total market value and 50% in volume (Serrepuy, 2011). The impact of the launch of a generic can alter the rate of substitution of the brand molecule up to 80%, and in some countries up to 95%, a few weeks after the expiry date of the patent (Serrepuy, 2011). Ultimately, public payers have simply refused to bear the

risks associated with the development of highly priced, new molecules, by transferring most of these risks and costs to the pharmaceutical companies. This negatively influences the development costs and the innovation rate of the whole industry.

The growing aversion to risk of regulatory agencies responsible for product patents and registration is another factor that directly impacts on the development costs and time to market for new molecules. Pharmaceutical companies have to adapt quickly to these new expectations by increasing pre-clinical trials and post-launch trials to ensure the absence of serious side effects (PhRMA, 2011). These clinical trials obviously increase the development costs and have even led to the abandonment of certain innovation techniques. In 2010, the registration and launch of nearly 50% of new molecules approved by the FDA were delayed. In 2010, several products positioned as a potential major source of growth seriously suffered due to legislation (Towse and alii, 2012). For instance, (since July 2008), the Scientific Committee of the FDA requires laboratories to conduct long term clinical trials concerning all candidate drugs targeting type II diabetes in order to eliminate cardiovascular risk. Even when no safety problem has occurred in Phase II/III, these tests will last at least 2.5 years during pre-launch and 3 to 5 years after launch, which increases the development costs. Therefore, the life cycle of drugs has been shortened and the potential benefits considerably reduced.

A set of internal factors also put pressure on big pharmaceutical companies to reinvent their business models to sustain their productivity in R&D and innovation; the loss of patents and a drying up of the pipeline.

One of the prime factors that undermines the short and medium term growth of Big Pharma is the loss of many blockbuster patents, which were the basis of the traditional business model of these companies, coupled with declining productivity of R&D. In 2012 the loss of patents will account for 46 billion USD (compared to 39 Billion in 2011) Meanwhile, up to 60% of some Big Pharma's income (e.g. AstraZeneca) is threatened by the loss of patents and the arrival of generics in the short term (EFPIA, 2011). The generic market displays a growth rate twice that of the general pharmaceutical market (respectively 14-15% against 5-6% average annual growth rate estimated for 2008-2011 in terms of value) (Serrepuy, 2011).

That's why R&D should compensate for future patent loss. In contrast the pipeline of products in development of a majority of Big Pharma are impoverished, with a productivity of R&D that has generally continued to decline (EFPIA). In the last 90 years, between 30 and 40

new drugs were approved every year by the FDA, this number dropped to 28 molecules in 2011. The R&D costs have more than doubled and productivity has been divided by about 4.

Today, the development cycle of a new drug costs between $800 million and $1.2 billion. From 2000 to 2010, the number of molecules in Phase III rose from 369 to 539, representing a growth of 46%. But the balance in the ability to innovate has greatly changed in favor of biotechnology companies as they represented 70% of the Phase III pipeline in 2011 (EFPIA, 2011) Long underestimated by most Big Pharma, biotech products are now and will be in the medium/long term the drivers of R&D and innovation for the pharmaceutical industry. An estimated 40 to 50% of molecules approved by the FDA today are coming from biotech, this share almost reached 75% in the very high growth oncology market (PhRMA, 2011) Advances in scientific knowledge in biotechnologies applied to health have created a shift in the dominant paradigm in the pharmaceutical industry, leading companies to revisit and profoundly modify their R&D and innovation processes. This new set of coherent scientific principles offers the possibility to act not only on the effects of pathologies but also on their causes (Cockburn and alii, 1999). As a consequence, a new R&D process called “rational drug design” (with “feedback loops”) which is based on methods which are more deductive, formalized and planned progressively replaces the former traditional linear process of massive screening of molecules along sequential phases.

This “revolution” also led big pharmaceutical companies to revisit their R&D objectives and to adopt new models to fuel their growth, moving from the classic “major blockbusters” towards the development of specialty drugs, “niche blockbusters” and “multi-busters”(Hamdouch et Depret, 2011). Big pharmaceutical companies have missed this biotech revolution at least in its early stage and are engaged in a race to position themselves in this new paradigm. This has led to a wave of partnerships and acquisitions of (smaller) biotech companies and major mergers between pharmaceutical companies.

1.2- CHANGES IN INDUSTRY STRUCTURE AND COMPETITION.

As a consequence of the innovation crisis and the evolution of the “paradigm”, the pharmaceutical industry is marked by numerous (horizontal) integration strategies of big companies seeking scale and scope economies, through mergers and acquisitions while developing partnerships and networks (Bobulescu, Soulas, 2006). The first strategy which aims to strengthen market power rests on the classical approach of competition within the chemical paradigm, consisting of struggling against the drying up of innovation pipelines, and

the lack of R&D productivity. As a consequence, competing for market share, costs, prices and services due to incremental innovations and, when possible, to differentiate and target more profitable market segments. Mergers and acquisitions are viewed as a powerful vehicle to sustain this strategy; rationalize product lines and the value chain, to benefit from marketing and sales force rationalization and to find a compromise between short term profitability and the need to rebalance the product-market portfolios. Another objective would be to reduce the number of competitors (Dehry, 1997, Michelli, Kohler, 2000. This has led to a concentration of the pharmaceutical industry. On the organizational side, mergers and acquisitions led to rationalizations in R&D departments to avoid duplication, by reducing the number of R&D centers, and concentrating R&D efforts on the most promising innovations. At the same time, the race for innovation and the need to position them in the new bio-pharmaceutical paradigm led big pharmaceutical companies to acquire but also to establish partnerships with small biotech firms. The main objectives are to access new technologies and markets and also to increase their flexibility in facing uncertain markets. As mentioned above, big pharmaceutical companies missed the bio revolution and were often unable to acquire and develop new knowledge in these fields internally, notably because of their organizational structure and routines that were incompatible with the new ones and because of their inability to change their business models accordingly and swiftly (Larue de Tournemine, 1991). This led to changes in the "competitive game" around a model of "cooperation and competition" with each major player establishing and managing a sufficiently strong portfolio of partnerships to be able to take part in the scientific, technical, industrial and commercial stakes of new biotechnologies. Competition in the field of biotechnologies seems to be evolving towards a wide and collective competition: "it is no longer a question of innovating to compete, but competing to cooperate, in order to innovate together. It is now a race to innovate that is also a race to cooperate" (Hamdouch and Depret, 2000, p.15). This race to cooperate is strategically important because once the agreement has been signed it does not allow (during a given period of time) a change of partner, "locking" them into the cooperation process. This strategy is becoming more common as the progress in biotechnological knowledge becomes more uncertain, which results in high costs that cannot, in case of failure, be (re) covered (Bartoli, 2000). Win-win vertical partnerships that are organized on "a projects - based" approach enable biotechnological companies, (performing upstream research) to find results in their applied research, whereas pharmaceutical firms manage the stages of large-scale commercial development (Gambardella, 1995).

Consequently, big pharmaceutical companies are reorganizing their R&D activities and organizational structure to enable them to be both more efficient and increase their R&D and innovation productivity (ex: internally oriented process and structures) and to be more effective in their efforts to take a leading position in the bio-pharmaceutical paradigm (externally oriented process and structures) (Bobulescu, Soulas, 2007). The only solution for firms that have not formed partnerships with biotechnology firms, and would like to take part in bio-pharmaceutical research activity, is, therefore, to establish links with or to take over a competitor that has established a portfolio of strong alliances and partnerships. Table 1 presents some characteristics of the Re-organization of R&D in selected big pharmaceutical companies, focusing on internally oriented solutions.

1.3. REVISITING ORGANIZATIONAL DESIGNS FOR R&D AND INNOVATION

The characteristics of organizational designs for R&D in technology and science - based companies have been identified. In their study of organizational structures for R&D in 14 leading companies in six technology based industries (2 companies in medical/ pharmaceuticals), De Sanctis and alii (2006) point out the traditional dilemma and tensions between (a) decentralized organizational structures and formal R&D accountability to bring about more incremental product innovations and (b) the need for more centralized and informal R&D to sustain major technology advancement. They state that "companies continuously struggle with how best to reconcile these competing pressures associated with organizing R&D around science versus organizing R&D around products or markets (p.56). The authors found that "integrated and network designs are associated with lower costs and greater value generation from R&D relative to decentralized designs (p.58) and that each category (and its variants) has its own advantages and disadvantages. The first case in medical/pharmaceutical (Company B) shows a decentralized model while the second (company X) an integrated one. In integrated models, the typical CRD includes dedicated research project teams, laboratories and functional support groups. Company X has only central R&D, with a large Corporate Research and development (CRD) unit with many laboratories and functional groups. "CRD is responsible for supporting the R&D needs of the corporation and promoting new product development both short term and long term" and (p.61) , and company X creates "ad hoc" project teams with CRD personnel to address specific needs (in division business units).

Table 1. Re-organizing R&D in Big pharmaceutical companies: examples

	Pfizer (N°1 globally)	GSK (N°2 globally)	Roche (N°5 globally)	Merck & Co (n°8 globally)
R&D Pharma 2007	5 billion €	4.3 billion €	4.6 billion €	3.3 billion €
Organization of R&D	Reduction of R&D Centers : 11 to 4 USA: 1 R&D center in Groton, 1. research center in Saint-Louis, 1. development site in La Jolla. UK: 1. development site India: 1. clinical center China: 1 clinical center.	R&D reorganization in 2000: 8 CEDD (Centers of Excellence for Drug Discovery): 3 in UK, 1 in Italia, 3 in USA and 1 in Singapore. Furthermore, a new R&D center in Shanghai	R&D reorganization in 5 DBA (Disease Biology Area): 2 in Switzerland (SNC, Metabolism), 3 in USA (inflammatory diseases, Oncology, virology), from research to commercialization. China : one clinical and one Development site.	Research in Boston 12 development sites: 5 in USA, 1 in Canada, 5 in Europe, 1 Japan.
Acquisitions referred to R&D 'Ex)	2007. 2 biotechs: CovX - Bio Rexis Pharmaceuticals (2006. 1 biotech US: Rinat, 1 biotech in UK: Powderedb Acquisition Of 4% in Nicox. 2005. 4 biotechs in USA: Angiosyn, Vicuron Bioren, Idun Pharmaceuticals.	2007. Reliant pharmaceuticals, 2006. Dominatis, integrated within CEDD "Biopharmaceutical Activities" 2005. ID Biomedical and Corixa Coyoratim	2008. Ventana Medical Systems (USA) specialized biotech in oncology diagnostic 2007. 454 Life Science (High Speed DNA Sequencing)	2006. 3 biotechs US : Glycofi (Abmaxis (and Sirna (2004. Aton Pharma (US) 2001. Rosetta Informatics

1.4. IMPLICATIONS FOR STRATEGIC AND ORGANIZATIONAL CHANGE.

Many researchers have addressed the implications of change in the "drug discovery paradigm" in terms of strategy and organizational structures. Big pharmaceutical companies have progressively shifted the focus from conventional internally oriented to more "open" innovation processes (including partnerships, strategic alliances, networks and even open-source (Niman, Kench, 2003)) that are propitious to -internal-external- cross fertilization of knowledge and to the improvement of R&D's productivity. This revolution led to major changes in their strategy and organizational structures, leading to "new business models"

In their study of the history of drug discovery in the pharmaceutical industry Henderson, Orsenigo and Pisano (1999) identified the transformation (revolution) that took place in the 1990s and its orientation towards "molecular biology". This "revolution" called for the development of new organizational arrangements and change within pharmaceutical

companies, moving from traditional and internally oriented models to more "open" ones. This led to the development and multiplication of partnerships and networks (Orsenigo, Pammoli, Riccaboni, 2001). Cockburn (2004) showed that these changes in the nature of R&D activities induced complementary changes in the internal structure of pharmaceutical companies which were more oriented towards academia putting emphasis on collaboration, networks and exchange of pre competitive information. Henderson and Cockburn (1996) discuss the role of scale, scope and knowledge spillovers as determinants of productivity in drug discovery. They show, *for example*, that economies of scope have an important impact on R&D productivity and insist on the role of (internal) knowledge sharing and transfer. In their study on the diffusion of science driven drug discovery in the pharmaceutical industry between 1980 and 1993, Cockburn, Henderson and Stern (1999) indicate that the industry has progressively shifted from a traditional approach (massive screening) to a more science driven drug discovery. The analysis shows that adoption of this new approach is a function of initial conditions (higher level of science orientation), and that it took time for companies to adopt new organizational practices and implement organizational changes. The relative diffusion rates depend on the firm's activities and positioning (product-markets) and the adoption rates are separately driven by the composition of sales. The research suggests the "potential importance of differences among firms in terms of the internal structure of power and attention". More specifically the qualitative part of this research (interviews in 7 companies between 1998-1999) indicates that the costs of adopting (switching to) the new science based approach was significantly lower for companies which, *for example*, were already committed to pure research and encouraged publications, had experiences in working with university labs, were located close to complementary publicly funded institutions facilitating the transfer of knowledge, had developed a clear vision and leadership to support the change process and where early success triggered the diffusion of change within these organizations.

Building her research on (e.g.) Henderson and Cockburn (1996), Charue-Duboc (2006) developed a theoretical framework to better understand the organization of the R&D function and its efficiency. The author introduces the absorptive capacity (Cohen, Levinthal, 1990) and its associated internal and external technical knowledge, accumulation, transfer and sharing as a key dimension contributing to R&D's innovative performance. Both the internal structuring of R&D and cross project learning mechanisms have a direct impact on economies of scope and absorptive capacity - economies of scope and absorptive capacity impact on the performance. This in-depth longitudinal case study on organizational change in R&D projects in a big chemical/pharmaceutical company indicates that "in the pharmaceutical division'

research center, the internal structure reflects the external structuring of academic disciplines"… Areas of expertise and departments were no longer defined along therapeutic targets (close to the project scope, as was the case before the reorganization) but according to existing areas of academic specialization (micro-biology, immunology, molecular biology)" (p.468). "The internal structure of R&D mirroring academic disciplines was also emphasized as favoring relations with external entities. This organizational change aimed at reinforcing competencies by promoting more links with new developments in the discipline. (p. 469). Downstream cross projects organizational learning mechanisms are put in place (e.g.) to transfer knowledge and standardize R&D methods.

1.5. THE CONTEXT OF THE STUDY: STRATEGIC AND ORGANIZATIONAL CHANGE AT ROCHE

The adoption of the new biopharmaceutical paradigm led to a new approach of medicine. Long considered as an "industrial product", drugs became a health service. Roche integrates this new dimension in its Pharma 2015 project, placing the patient at the very center of its innovation process: Both more targeted biomedical expertise and the development of diagnosis are driving the new mission: "We innovate Healthcare".

As a consequence, a new organization of Research and Development has been implemented within Roche in 2007. The decision was made to abandon the hierarchical functional structure and to adopt an organizational structure that is aligned with the new innovation process described above to increase R&D and innovation's productivity. The new structure is a matrix organization in five autonomous DBAs (Disease Biology Areas).The new model is designed to ensure that Roche's steadily expanding R&D operation is suitably equipped to meet increasingly complex requirements. By simplifying and accelerating the multiple decision-making processes involved, the model would be more efficient and effective in translating research activity in each therapeutic area into clinically differentiated medicines. It also enables to better integrate the Group's growing number of development projects. Each DBA covers the whole range of activities from R&D to strategic marketing in a specific therapeutic field. There are five specific therapeutic fields: -Oncology, DBLT based in Nutley, New Jersey, USA - Virology, DBLT based in Palo Alto, California, USA -Inflammation, DBLT based in Palo Alto, California, USA -Metabolism, DBLT based in Basel, Switzerland -Central Nervous System, DBLT based in Basel, Switzerland. Table 2 which is drawn from internal reflections in Roche and confirmed by a "benchmark" study led by our team of students on a panel of 5 pharmaceutical laboratories : IPSEN BEAUFOUR, GSK, SANOFI, NOVARTIS

and LILLY enables the presentation of the advantages and disadvantages of the matrix organization.

Table 2. Potential advantages and disadvantages of the matrix organization

Strengths of a Matrix organization	Weaknesses of a Matrix organization
Leverages functional economies of scale while remaining small and task focused	Violates the principle that authority should equal responsibility
Focuses employees on multiple business goals	Violates the principle that every subordinate should be assigned to a single boss
Facilitates innovation solutions to complex, technical problems	Can create ambiguity and conflict
Improves employees companywide focus through increased responsibility and decision making	Increases costs resulting from the need for additional management and administration
Allows for quick and easy transfer of resources	Increases likelihood of resistance to change as employees may attribute the matrix with loss of status, authority, and control over traditional domain
Increases information flow through the creation of lateral communication channels	
Enhances personal communication skills	

2- RESEARCH QUESTIONS AND METHODOLOGY.

In 2009, the Global Head of Pharma Development and Chief Medical Officer at Roche offered a group of five students from the Esc Dijon- Bourgogne (Burgundy School of Business) ' Master in Management of Pharmaceutical Industry the opportunity to conduct an analysis of this project that had been launched in 2007. One of the main concerns was to help define a set of criteria to assess progress made in increasing R&D and innovation' productivity, thanks to the new organization. A second set of (related) issues was - to assess how key actors perceive strategic and organizational change, -to identify levers and obstacles in their implementation and alignment. This led to the formulation, (in close cooperation with Roche) of two research questions to be addressed. -What are the central dimensions which contribute to sustaining change? How do key actors perceive progress made (levers and obstacles/difficulties)?

2.1-THE BURKE AND LITWIN'S CAUSAL MODEL OF PERFORMANCE AND CHANGE.

A decision was made (in close cooperation with Roche) to use the Burke and Litwin's (1992) model as a guide to conduct the empirical research and to interpret its findings and results. This model suits the context faced by big pharmaceutical companies presented above and addresses the research questions for the following reasons. - It is based on the premise that changes in external (environmental) factors act as driving forces leading to strategic and organizational changes, "putting pressures" on companies and triggering the change process and, consequently, have an impact on individual and organizational performances. It identifies 12 inter-related (and cascading from long to short term) factors which form a system and have an impact on the 12th variable; individual and organizational performance. These variables fall into two categories: transformational and transactional. Transformational factors are long term oriented and cover the company's vision, mission, strategy, culture and leadership. These factors cascade through (mid-term) transactional ones such as organizational structures, managerial practices and processes and finally, (short term) team or individual factors like the team's climate, job/person's fit, motivation, needs and competences. Figure 1 presents the model as well as the key dimensions addressed in this study. We added the terms Vision (we associated with Mission) and "corporate values"(associated with organizational culture) which have not been used by Burke and Litwin.

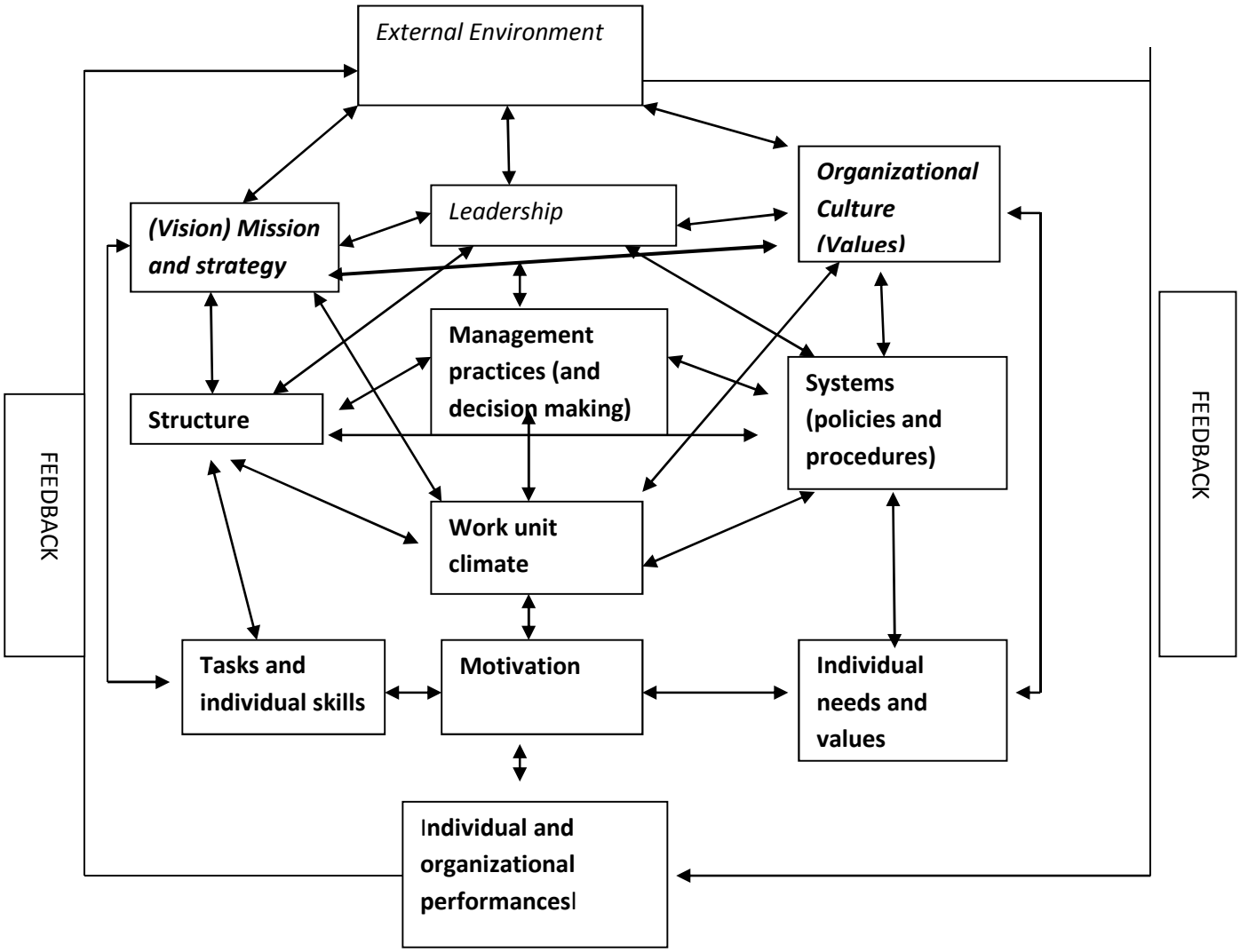
2.2- DATA COLLECTION

Data collection has been performed thanks to a questionnaire–based survey. The questionnaire comprises three types of questions relating to the selected factors identified in the Burke and Litwin 'model. – A set of "closed" questions to (1) assess participants' perceptions and attitudes about change- (ex: positive, negative, neutral) – Rating scale (Likert scale) to identify levers and obstacles – Open questions to identify the participants 'perceptions regarding the most important benefits of the change process and how it could be improved. Sixty two questionnaires have been received and analyzed. Table 3 presents the distribution of respondents.

Table 3. Sample (respondents) description

Seniority in the Company (n of years)	n > 5 years = 61%, 2< n< 5 = 13%, n<2 = 26%
Job level	Leadership : 50%, Manager : 23%, Specialist : 27%

Figure 1. The Burke and Litwin model: *Transformational (in italics)* and transactional factors - key factors analyzed in this study (**in bold)**
(adapted from Burke and Litwin, 1992, p.528)



3- RESULTS.

This section presents and briefly discusses the results (descriptive statistics) drawn from this study. Starting with the respondents' perceptions regarding the whole project (Pharma 2015) it reviews key transformational and transactional dimensions identified in the Burke and Litwin model as well as their relations.

3.1- PHARMA 2015.

The survey contains questions to assess the respondents' perceptions regarding the implementation of Pharma 2015. The first question (presented here) aims at identifying how participants perceive progress made and how the project impacts on their daily work. The second set of (open) questions enables the identification of the levers and obstacles relating to key variables presented in the Burke and Litwin model.

Descriptive statistics show that a significant majority of respondents (81%) think that the implementation of Project 2015 has improved (10%) or will improve (71%) the situation. However, the implementation takes a lot of time and effort ("useless" for 14% and "worthwhile" for 71%). This result, (after a period of two years) indicates that, even if respondents are positive about the change process induced by Pharma 2015, they are (still) facing a lot of obstacles

Table 4. Pharma 2015: Changes

Propositions	%
It (the situation) is worse than before	3
It takes lot of time and effort but respondents do not think it (the situation) will improve	14
Nothing has changed	2
It takes a lot of time and effort but respondents think that it (the situation) will be improved	71
Everything is improved and better than before	10

The impacts of change (improvement: 6 positions ranging from no improvement to strong improvement) have been identified in different fields relating to transactional factors associated with daily work as table 4 shows. Even if improvements are perceived in all dimensions (Scores > 4), very positive improvements have been made in decision making and problem solving, while opinions regarding improvements in communication and information exchange are more mitigated (taking into account Scores 5-6)

Table 5 : Perceived improvements

n= number of respondents (N=62)	1 No improvement	2	3	4	5	6 Strong improvement
Communication within Team/department	1	7	15	24	11	4
Information exchange between teams/departments	2	5	17	24	11	3
Clarity of functions departments/teams	3	11	14	20	11	1
Problem solving	3	3	15	23	17	1
Quality of decisions	2	4	16	18	19	3
Performance team/department	1	3	12	30	12	4

There are positive relations (correl coefficients >0.5) between perceived improvements in communication, information exchange, clarity of functions, problem solving, quality of decisions and performances. This suggests that if respondents perceive an improvement in one dimension, they also perceive improvements in others.

3.2- TRANSFORMATIONAL FACTORS.

Transformational factors cover Roche's vision, mission, strategy, culture and the relationships between them.

3.2.1 Vision

Descriptive statistics show that the new vision is very attractive for 84 % of respondents. This suggests that the vision is well understood (and shared) and communicated.

3.2.2. Strategy deployment.

The objective was to assess how respondents perceive the way the new strategy has been deployed. More specifically, respondents were asked to assess to what extent this strategy is perceived as being clear and properly communicated (scale ranging from very ambiguous (1) to very clear (6)), depending on their role in the company (as leaders, managers or specialists)
As shown in table 6, 41% of respondents (5 and 6) think that the strategy is really clear, only 7% believe the strategy is very ambiguous while 52% (3 and 4) have mixed opinions. The majority of employees understand the strategies of Roche. 57% of the managers is positive about the clarity of the strategy, 49% of the leaders is positive and only 18% of the specialist. This result indicates that the more respondents are working on an operational level, the more the strategy becomes ambiguous. (With a correlation coefficient of 0.58)

Table 6. Strategy

	1 very ambiguous	2	3	4	5	6 Very clear
All respondents %	2	5	26	26	35	6
Leaders %	0	7	20	18	45	10
Managers %	0	0	15	30	55	0
Specialists %	5	5	45	26	13	6

3.2.3. Culture and (shared) values;

The objective was to assess how respondents perceive the difficulties to understand Roche's cultural traits and values (six positions ranging from difficult (1) to easy (6)), and whether these values correspond to their own values (six positions ranging from very different (1) to very similar (6)).

Answers to these questions can be considered as indicators of the role of corporate culture as a transformational factor. "Easiness" in the understanding of corporate culture, coupled with similarity between corporate and personal values (as an indicator of shared values) are conducive to a better alignment between transformational factors, (which are stable variables).

Table 7. Corporate culture and shared values (% ,n=62)

Roche culture* From very difficult to understand (1) to very easy (6)	1= 2% , 2=10%, 3= 19%, 4= 32%, 5= 27%, 6= 10% (**<= 3: 31%** >= **4: 69%**)
Roche values – own values From very different (1) to very similar (6)	1=0%, 2= 7%, 3=13%,4= 21%, 5= 53% 6= 6% (<= 3::**20%, >=4 : 80%**)

*, participants were asked to take the position of a newcomer in the company.

Descriptive statistics show that (1) the (great) majority of respondents, perceive that Roche' culture is easy (or not that difficult) to understand. However, (only) 37 % strongly agree (5 and 6) and 12% consider that it is difficult (for a newcomer) to understand (and, possibly, as a consequence to rapidly adhere to) Roche's culture. The fact that respondents work in the company would reduce this gap, as their answer to the second question suggests. Importantly, the (great) majority of respondents perceive corporate and personal values as being very similar (and as a consequence (probably) shared) (60% (5-6))

3.3. TRANSACTIONAL FACTORS

The design and implementation of a new organizational structure is central in the Project 2015' framework. It aims at creating a context that is aligned with the transformational factors and can be viewed as a hinge or a cornerstone between transformational and transactional factors. This section briefly presents and discusses findings drawn from the survey as they relate to the Burke and Litwin's model. As it was the case for the transformational factors, each dimension can be viewed as a lever or an obstacle to change.

3.3.1. Organizational structure.

Organizational structure has to do with organizational design, (overall matrix structure and projects), communication within and between units (departments, teams), and their relations or impact on other transactional variables (decision making, motivation, etc.)

A way to assess perceptions regarding the (overall) organizational design, is to identify whether it is perceived as being complex (score 1) or very simple (score 6).

Table 8. Perceived complexity of the organizational structure.

Complexity	1 Very complex	2	3	4	5	6 Very simple
% of respondents	8	40	29	18	5	0

The great majority of respondents think that the structure is complex (77% score>= 3) and, among them 48% state that it is very complex. However, there is a (mixed) agreement that Pharma 2015 has brought a better organization (Cor coef.0.32) and a positive relation between improvements in communication and the positive perception about the new structure (clarity of functions/responsibilities/tasks attributed to departments and teams) (coef. 0.437)

The analysis led to the conclusion that a set of key questions must be addressed and answered – why do Roche employees perceive the new structure as being complex? – Should the interfaces (and connections) between departments and teams be clarified and made more transparent?

3.3.2. Relations between transactional factors.

Questions were asked to assess the relations between factors relating to the organizational structure (as a new context) and other transactional factors such as systems (processes)-decision making – project team-work, motivation and performance.

Systems

As a transactional factor, system (policies and procedures) is related to structure, decision making and work unit climate. The implementation of the new matrix structure (which is (as it has been outlined in the previous section) perceived as being complex) led to the

establishment of new processes within Roche. As shown in table 9 a great majority of respondents think that there are too many processes (scores >=4 : 88%, >=5:62%)
Results are slightly different depending on their position in the company, more specifically for leaders (>=5: 71%) and to a lesser extent, specialists (>=5: 59%)

Table 9. Processes

Processes	1 Too few	2	3	4	5	6.Too many
Sample	0	1	11	26	31	31
Leaders	0	3	10	16	29	42
Managers	0	1	7	50	21	21
Specialists			17	24	41	18

Management systems and decision making

Management systems (and decision-making) are transactional factors, which, coupled with structure and processes are related to work unit climate, which, in turn, is directly related to motivation, and as a consequence to performance.

Decision making

A central objective of the new matrix structure is to reach the right balance between R&D led in teams (upstream) and departments (downstream).
According to the survey, a majority of respondents think that the new structure has led teams to have or exercise more power/influence than departments in decision making (scale 6 positions from departments/functions (1) to Teams(6). The great majority of respondents perceive (69% >=4) - strongly (42%>=5)) that project teams have more influence on decisions, and only 18% (scores 1-2) think that departments have more influence. However, perceptions depend on the respondents' positions as leaders, managers or specialists. Leaders clearly think that power in decision making has shifted in favor of teams (their favor) (51% >= 5), while managers and specialists' perceptions are more balanced. Finally, it is worth noting here that there is a positive relation between decision making and the improvement of performances (team / department) (corr coef.0.4)

Table 10. Perceived change in decision-making

Influence in decision making	1. Department	2	3	4	5	6 Teams
Sample %	2	16	13	27	37	5
Leaders %	0	10	13	26	48	3
Managers%	0	21	21	29	29	0
Specialists%	6	24	6	29	24	12

Work unit (teams) climate.

As a transactional factor in the Burke and Litwin model, work unit climate is related to structures and decision making and factors such as systems, and motivation.

The survey investigates how respondents perceive this work climate and more specifically how they assess team work and climate as being more oriented towards competition (19% of respondents) or towards cooperation (66%).

A second dimension which has an influence on work climate (and vice versa) relate to management practices. It (e.g.) covers incentives, like rewards (compensation and benefits, career development) and the quality of relationships with management. These factors through their impact on work climate, contribute to increased motivation.

Motivation

Motivation is central in the model, and is directly related to work climate but also to individual-tasks and skills, - needs and values. Respondents were asked to rank (by importance from very high to very low) a set of incentives having an impact on motivation.. Table XX presents this ranking and their corresponding transactional factors.

Table 11. Incentives/ Motivation

	Rank	Transactional factors associated to Motivation
Scientific and intellectual challenges	1	Individual **needs**, **skills/tasks**
Contribution to society	2	Individual **values**
Work climate	2	**Work climate**
Compensation (financial) and benefits	3	Management practices (influence through **work climate**), **individual needs**
Career development/recognition	4	**Individual needs** (management practices, via work climate)
Competency development	5	**Individual needs, Skills/tasks**
Relationship with management (quality)	6	**Work climate**

The ranking of different incentives influencing job motivation shows that scientific and intellectual challenges are the absolute number one driver (for 27% of respondents). This suggests that the adoption of the new bio pharmaceutical paradigm in the Pharma 2015 project brought new scientific and intellectual challenges that are perceived as incentives and would increase motivation responding to individual needs and impacting on skills and tasks (enrichment). Contribution to society, which is ranked number two, deserves comment. It is ranked at the top by a group of respondents and at the bottom by another (smaller) group. Such is also the case for compensation. This suggests there is diversity in coworkers' motivations.

4. CONCLUSIONS

The objective of this research was to identify levers and obstacles in the (early) implementation of the new organization that has been put in place in the framework of the Pharma2015 project to improve R&D and innovation and to position the company in the new biopharmaceutical paradigm. This new organization was as an intermediate step for Roche. The analysis shows that transformational factors identified in the Burke and Litwin 'model of change" and which are oriented towards the long term, are related and integrated in the Pharma 2015 project, and perceived as such by a great majority of actors. These stable dimensions orient and facilitate changes in the organizational structure and its alignment. The new organizational design (and its related dimensions) aimed at creating a context propitious to fuel R&D and innovations, improve their productivity and to pave the way towards the adoption of the new biopharmaceutical paradigm. The new matrix structure can be viewed as the cornerstone between transformational and transactional factors. Organizational designs and structures cover "stable" (design) and dynamic dimensions and are oriented towards the mid-term, enabling the cascade of transformational factors within the organization and creating a context in which the dynamic and more short term oriented transactional variables interplay.

The characteristics of this new organization are perceived as levers but could also be obstacles due to their (perceived) complexity. Finally the analysis of our case indicates that some transactional factors (and their relations) like work climate and motivation play a central role in the strategic alignment of the dynamic transactional variables and the transformational ones.

Transformation at Roche between 2007 and 2009 can be viewed as a transition towards the new biopharmaceutical paradigm, marked by the full acquisition of the biotechnological company Genentech in 2010 and its integration in to Roche. One of the main concerns was not to "lose" the dynamics of innovation which characterizes this company and how to "merge" two very different organizational cultures. This opens avenues to investigate a new set of research questions - Has the integration of two distinct organizational models facilitated innovation or revealed new obstacles? – Has this acquisition led to evolution in the organizational (matrix) structure at Roche, or to a new organization and how are these changes perceived by R&D teams?

REFERENCES

Bobulescu, R. and Soulas, C., (2007) . Biotechnologies and innovating strategies in the pharmaceutical industry, *Journal of Pharmaceutical Finance, Economics and Policy,* Volume 16, Number 2: 43-60..

Bobulescu, R. and Céline Soulas, C. (2006). Innovation and firm size in the pharmaceutical industry, *International Journal of Business Environment,* Vol. 1, No. 2. : 253-64.

Burke, W. and Litwin, G. (1992) A causal model of organizational performance and change, *Journal of Management,* 18-3, 523-545

Charue-Duboc, F. (2006) A theoretical framework for understanding the organisation of the R&D function: an empirical illustration from the chemical and pharmaceutical industry. *International Journal of Innovation Management* 10-4 ; 55–476

Cockburn, I M., (2004), The Changing Structure of the Pharmaceutical Industry," *Health Affairs, 23(1): 10-22.*

Cockburn, I., Henderson, R., and Stern, S. (1999) The diffusion of science driven drug discovery: organizational change in pharmaceutical research. *National Bureau of Economic Research* Working Paper 7359, Cambridge Mass. 1-53

Cohen, W. and Levinthal D. (1990) Absorptive capacity : a new perspective on learning and innovation. *Administrative Science Quarterly,* 35, 128-152

Cowley , B. (2007) Why change succeeds: an organizational self assessment, *Organization development journal*, 25-1, 25-30

De Sanctis, G., Glass, J., and Morris Ensing , I., (2002) Organizational designs for R&D *Academy of Management Executive,* Vol 16-3, 55-66

Drummond M. (2012). Twenty Years of Using Economic Evaluations for Reimbursement Decisions. What Have We Achieved?, York University.

EFPIA (2011), The pharmaceutical industry in Figures.

Hamdouch A. and Depret MH. (2001), « La nouvelle économie industrielle de la pharmacie : structures industrielles, dynamique d'innovation et stratégies commerciales, Elsevier, Biocampus, Paris.

Henderson, R., and Cockburn, I., (1996) Scale scope and spillovers: the determinants of research productivity in a drug discovery. *Rand Journal of Economy,* 27-1, 32-59

Henderson, R., Orsenigo, L., and Pisano, G.P., (1999). The pharmaceutical industry and the revolution in molecular biology: exploring the interactions between scientific institutional and organizational change, In: Mowery, D.C., Nelson, R.R. (Eds)., *The Sources of Industrial Leadership* , Cambridge University. Press, Cambridge, MA.

Niman, N.B. and Kench, B.T. (2003)., Open source in the pharmaceutical industry, *Proceedings of the Midwest Business Economics Association* lacal.net/files/NIMAN-KENCH.doc

Orsenigo, L., Pammolli, F., and Riccaboni . M. (2001) Technological change and network dynamics: Lessons from the pharmaceutical industry. *Research Policy 30 485–508*

PhRMA (2011), Industry Profile.

Serrepuy, S., (2011), Médicaments génériques : le marché de toutes les attentions, Pharmaceutiques, 182 - Supplément , pp: 42-43.

Towse A., Garrison L.P. and Puig-Peiro R. (2012), The Use of Pay-for-Performance for Drugs: Can It Improve Incentives for Innovation? , London : OHE.