Case studies

Strategic and organizational innovations in the pharmaceutical industry – searching for total quality: the case of a large European pharmaceutical company

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Abstract

When considering the traditional conceptions of strategy and quality, the links between the two concepts appear sketchy. On the other hand, nowadays, the main streams of thought lead to a necessary and complementary relationship between total quality and strategic management. The pharmaceutical industry, because of the stakes implied by the activity itself, is particularly concerned with the links between quality and strategy: the example of the large European group Merck-Lipha appears quite significant.

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If, in certain countries, total quality seems to have become outdated, this is not the case in Europe where the movement is being reinforced and developed in many branches of industry. The terminology may have evolved but the spirit of process improvement and quality management is increasingly present.

For a long time reserved to the largest companies, the tidal wave of quality management reaches today many SME and even public sector organisations. As for the branches of industry concerned, they also diversify, as industries traditionally centered on "product quality" (such as the pharmaceutical sector) are starting to reconfigure their processes and to develop managerial strategies leaning toward "organisational excellence". One of the key factors of this development seems to be the ever increasing link between quality and strategy both in academic works and in professional practices.

Strategy and quality: which correlations?

In the traditional concepts of strategy and quality (those of the 1960s and 1970s in particular) the relations between these two concepts are not strong:

(1) On the one side, strategy is traditionally conceived as the choice of an external positioning (in terms of products on the markets). It is the case of the oldest trends (as in Harvard's "business policy" approach, Ansoff's "corporate strategy", or even the methods of competitive strategy of the large consulting firms such as BCG, McKinsey and ADL; but this exteriorized representation of the strategy can also be found in the works of more recent theorists such as Porter (1980).

(2) On the other side, quality refers to the product, apprehended accordingly primarily to technical procedures and standards. Thus, complex statistical tools have first been developed to control the product conformity; then the logic of quality assurance leads to the set-up of procedures and specifications to guarantee the obtaining of a certain level of quality and to allow the "certification" of the firm as viewed by its external partners (Couret *et al.*, 1995).

In this conception, quality is first of all the business of production and of internal

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logisticians, but is not usually positioned on a more global level. Indeed, the kind of quality sought for might correspond to a brand level which represents the adopted strategic positioning, but the relation "strategy-quality" usually stops there.

Today's concepts are completely different, at least in some professional environments. Also, the current tendencies lead to a necessary complementarity between total quality (or "global") and strategic management (Hermel, 1989). Indeed if strategy is defined as all alternatives leading to aim at a determined direction in the mid-to-long term for all activities and operations of the organization (Martinet, 1984), it assumes the orchestration of all entrepreneurial resources to create competitive advantages and a potential for evolution.

The organisational processes, their effectiveness and their fluidity, their impacts in terms of innovation, and their direct and indirect costs constitute first order strategic factors, which carry a logic of quality and excellence at all stages of the firm's operations.

Within this framework, several characteristics prove to be essential (Bartoli and Hermel, 1989):

- the articulation between internal dimensions (operations) and external dimensions (relationships to the environment) of the firm strategy;
- the key weight of the firm's actors in the strategic process;
- the integration of social, economic, technological, commercial, and informational factors for the strategic diagnosis and formalisation;
- the interaction between strategy, structures, cultures, and the behaviors in the firm;
- the concept of "strategic process" leading in particular the phases of implementation and piloting (and not only, as in the past, those of design and upstream decision).

Consequently, the majority of authors adopt the expression "strategic management" instead of the simple term of "strategy" giving it a more global and dynamic sound (Ansoff *et al.*, 1976; Koenig, 1990).

In parallel, the various designs of total quality – even if they are not homogeneous, in particular between the US (Crosby, 1984) and Japanese trends (Ishikawa, 1982) – present common features:

- a generalization of the concept of quality to all fields of the firm (not only the end product, but also all operational processes);
- an extrapolation of the customer-supplier relation to all the working and operational interfaces inside the firm;
- the implication of employees in the process of obtaining quality;
- the permanent search for improvement, aiming at reducing the gap towards the objectives to reach.

Today, the majority of works in management implicitly or explicitly show the connections between strategy, organization, and quality (Mintzberg, Drucker *et al.*). But where are the relations between strategy and quality really built?

The first connection is initially and above all linked to the need to choose. Strategy is about choice (of positioning, process, etc.) just as quality is relative and supposes choices to be made as to the level and the kind of quality to adopt. The overall coherence, and the image of the firm which results from this, thus are proved to be implicitly or explicitly factors of success.

Thus, since the 1990s, in Europe and France, processes of "strategic management of quality" are being set up. They more or less require answers to the following questions:

- What is the quality policy relating to: the end product; the intermediate products; all processes of the firm?
- What is the awaited, desired, sought after quality and how is it coherent with the general policy and the strategic positioning of the firm?
- How to obtain this quality? What process has to be installed? With what objectives? Which actors? Which action plans? Which indicators?
- How is it perceived inside as well as outside the firm?

Thus, as much in regard to strategic management as in regard to total quality, the key factors of success relate to the global approach, the dynamic of permanent evolution, the clarity of choices made, the role of the actors, the cross-functional processes, and the relevance of information systems and steering methods.

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In the two present trends of thought, such factors are regarded as necessary (although nonsufficient) and make it possible for the firm to be effective in a turbulent environment.

More generally, it is through the search for organisational effectiveness that we find the trigger to press. Thus, even for firms traditionally focused on technological advances (such as in, for example, robotics, aeronautics, cars, etc. ...), managerial dimensions appear increasingly as being strategic: the fluidity of processes, the implication and adaptation of the employees, organisational optimisation, the internal capacity to innovate, and project management are all major concerns to the managers and can be translated into the concept of strategic management of quality.

Actually, the firms most sensitive to these factors seem to be those whose activity is challenged by major changes, relating to the products, services, external regulations or requirements, methods or work processes, competition, etc.

Thus the pharmaceutical sector is probably in the front cabins of the train to transformation.

The case of the pharmaceutical sector: specific requirements of both change and global approach

The pharmaceutical industry in the world represents a considerable economic weight: the market is estimated at US$300,000 million, with a demand continuing to grow year after year (due in particular to the aging of population, evolution of life styles, appearance of new pathologies, prevention policies, etc.).

During the last decade, the industry structure changed considerably, going from a situation of significant atomization (with many laboratories of average size hyper-specialized on certain therapeutic families), to great phenomena of concentration, giving birth to very large world groups resulting from mega-mergers (Aventis, Novartis, Glaxo/Smithkline, Merck & Co, BMS, etc.).

Because of the stakes of its activity, at the crossroads of public health, social responsibility, and economic impact, the pharmaceutical industry is particularly concerned with quality. This subject concerns it in relation to several logics:

- Subject to many controls and authorisations from Authorities, the pharmaceutical laboratories implement extremely rigorous protocols, as much in early phases (research and development) as in the late phases (production and marketing).
- Processes of formal certification (according to the ISO standards for Europe) are taken in order to be able to guarantee to the "customers" (doctors, pharmacists groupings, organisations of health insurance, patients, etc. ...) the respect of strict procedures.
- Finally, because quality of the operational processes relies on coherence, fluidity, and the reliability of the operation of the firm as a whole, it is indeed an approach of total quality and of search for "Excellence" which is generally needed today in this activity.

To these general (and not all recent) characteristics are to be added some new aspects which shake this branch of industry which is at other times protected. Thus, the deficits of the public health systems (in particular in Europe) led to more strict requirements in market prices of drugs. For example, for a few years in France, governmental measures have led to falls of prices and falls of refunding rates of pharmaceutical products. The "Economic Committee of Health Products" (STOCKS) has been particularly focused for a few months on the control of negotiations with the actors of the health system to obtain for the next three years a significant reduction (20 percent on average) of the drug prices whose "given medical service" is considered to be insufficient. Moreover, in many cases, the refunding rate which social security applies is decreased, even being cancelled on some products.

Consequently, the "sensitivity to price" of the doctor, the pharmacist, and even of the patient increases considerably, after having been traditionally low or nil for decades.

Moreover, the development of generic drugs constitutes a form of acute competition for the traditional pharmaceutical products. Thus, on the pharmaceutical markets two types of products cohabit today:

(1) The "Princeps one": this is a drug coming from the product innovation of

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laboratories, generally patented and marketed under a brand name.

(2) The "Generics": this is a drug which has the same composition in active principle as the princeps drug, and which proved its "bio equivalence" and thus its interchangeability with the princeps one; generics can be marketed only after the expiration of the patent on the original drug.

This cohabitation is all the more a reality now that the national regulations evolved in order to support it. It is the case in France where, from 1999, the "right to substitute" authorises pharmacists to replace a brand drug prescribed by a doctor by its generic equivalent. This decree (resulting from the social security financing law voted in December 98) is accompanied by a financial incentive for pharmacists: thus, the pharmacists who commit themselves to replace 35 percent of substitutable prescribed drugs by generics profit from a new kind of remuneration allowing them to increase their net margin.

Such changes in the environment of the health sector bring many consequence for the industrialists in this sector, especially for those who have positioned themselves in the "Ethical" market (products prescribed by doctors):

- they have more direct customers and those are more diverse (not only doctors but also pharmacists);
- the competitive dimension is much stronger;
- the economic requirement becomes a main factor;
- the products' cycles of life are shortened;
- the internationalisation of markets is increasing.

Moreover, the alternative offers (biotechnologies, molecular engineering ...) lead to new questions, likely to become threats or opportunities according to the adopted strategic positioning.

Finally, the incapacity to act alone in such a complex field becomes clear and clarifies the need for alliances and cooperation on all levels.

Consequently, the laboratories of the pharmaceutical industry are led to entirely reconsider their strategic approach and to deeply question themselves if they do not want to disappear or to be completely absorbed. All the traditional bases of the development of this kind of activity are breaking down, leaving room for new key factors of success.

Confronted with those new requirements, some pharmaceutical companies engaged strategic management policies enabling them to build new adaptation capabilities for the future.

These new policies endeavour to combine several dimensions:

- a development of the innovation capabilities as well for the products and technologies as for procedures and relations between actors;
- a permanent search for "quality", or even excellence, relating not only to the final offering (products or services), but also to its early design, and the internal organisational processes.

The case of the European firm Merck Lipha is a clear illustration of those strategic, organisational and managerial innovations in the pharmaceutical industry.

Total quality at ML: a global project of strategic management

Context

Merck-Lipha (ML)L came from the merger in the early 1990s of a traditional European firm (Merck), created more than 300 years ago in Germany, and of a French SME (Lipha) created in 1942. With a payroll of more than 4,300 people, it carries out international consolidated sales figures of about US$1,150 million in 1999. In spite of this significant size, it is considered as being in the category of medium-size firms, taking into account the recent evolution of the structure of the pharmaceutical industry (especially since the mega-mergers).

After significant transformations in its teams, its field of activity, and its structures during the 1990s, the ML group became aware of the changes in progress in its environments, external as well as internal, and decided to build a federating project based on three essential principles, formulated as follows:

(1) a global offer of innovating services answering expressed desires of both prescribers and users of its products;
(2) a constant quality improvement;
(3) an objective of efficiency, thanks to an incentive social policy.

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In line with the policy of the main company (M) anchored around the slogan "That's ME Merck. Excellence", the firm "L" works out its strategic management project represented by Figure 1 (inspired by Bartoli and Hermel, 1989).

Within this framework, the firm "L" formulates its mission in the following way:

L promises:

- to bring solutions to the patients suffering from the treated syndrome (...) and its complications;
- to maintain a high rate of sustained growth and a constant profitability;
- to pursue a policy of internationalization and innovation, in terms of markets as well as in terms of products, culture or management.
- to develop the key values which are decentralization, flexibility, expertise and sense of responsibilities (information gained from internal documents of the firm Merck-Lipha).

The policy of total quality

During the 1990s, "L" decides to engage a voluntarist and proactive step in order to define how the firm conceives its perenniality (and concrete methods to reach it), basing itself on the evolution of its external and internal environments.

Indeed, in addition to the general evolutions known to the whole pharmaceutical sector, L must also face specific changes:

- new management board;
- a new structure of capital;
- entry on the financial market of the main stakeholder;
- acquisitions widening the fields of activity (not only "ethical" drugs but also generics and self medication).

In this very sensitive context, filled with uncertainties and complexity, L chooses to take the initiative in its transformations, to turn threats as much as possible into opportunities and to acquire, in time, the competences necessary to the future trades.

Strategic management then appears to be a possible answer to combine internal and external parameters. This answer is based on a policy of total quality, including:

- product quality (= search for zero-defect);
- quality insurance (= search for the zero-blocking in the firm organisation);
- total quality management (= search for continuous improvement and the reducing of dysfunctionalities profitable both to individual and firm).

Piloting the process

The firm began its strategic management process with a double move:

(1) working sessions at "board" level to establish a common language, to lay down objectives and planning;
(2) an internal diagnosis, involving all professional categories, to determine the needs and capacities in evolution.

A wide programme of formation-action to strategic management, centered on the piloting of change, was conceived and implemented for a five-year period, mandatory first for all the managing staff then for all the intermediate levels (technicians and assistants).

In parallel, participative actions are led within the various units of the firm in order to find new ways of reaching total quality. The whole managing board was involved in the plan, and questioned its own practices concerning dialogue and decision making.

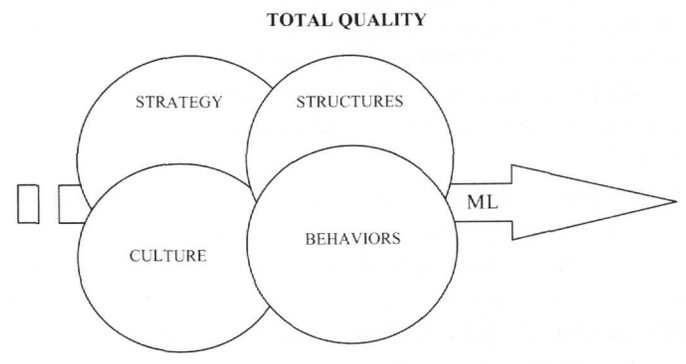
Finally actions of business process reengineering (Hammer and Champy, 1993) are being led, as much for direct efficiency (in terms of cost, quality, time), as for developing internal transversality.

Thus the following processes were entirely reconfigured:

- launches of new products;
- acquisitions of molecules licenses;
- marketing authorization;
- sales administration;
- purchases of marketing support and promotional products;
- clinical phase of molecules development;
- design and realisation of "packagings".

Engaged for five years in this new policy combining strategic management and total

Figure 1 Framework for strategic management project



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quality, the ML group felt better armed to face growing turbulences. Transversality enabled them to develop real synergies between "ethical" pharmaceutical activities (products on prescription), "OTC" (products advised by the pharmacist on request of the customer) and "generics". Moreover, the training necessary to all the mentioned change initiatives brought about a specific culture of adaptation and proactivity.

The economic results are very positive today, even if the management considers that the context still creates a situation of risk and brittleness.

On the domestic front, such a transformation could not be achieved without the appearance of some perverse effects. Beyond the positive evolutions (a more participative culture, greater responsibility and decompartmentalised operations) tensions might have appeared, and some cases of incapacity to adapt have revealed themselves.

Moreover, today, ML has sometimes a feeling of "boiling" a little too much and of having pushed the logic of adaptation and transversality almost too far. But this situation seems to correspond well, on the one hand, to the spirit of "total quality" which depends on regular adjustments, and on the other hand to strategic management which imposes a permanent control of achievements and the continuous measurement of their adequacy to a changing environment.

Strategy and quality thus prove to be closely dependent, as apprehended from the managerial point of view within a complex and changing environment. In fact from the example of the pharmaceutical industry arises the fact that the relevance of a "total quality" strategy depends largely on the quality of the strategic program and vice versa.

Under this light, the very concept of innovation takes on new significance. Beyond the development of new products and technologies to which the firms of all sectors are now accustomed, it is strategic, organisational and managerial innovations that we are now talking about, the objective being to unearth new levers on performance.

It remains to be seen whether the medium size pharmaceutical laboratories in the world will have the sufficient capacity, even with such levers, to preserve their identity and their relative independence.

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Commentary

Innovation, strategy and quality – important insights into the interrelationships between these three key factors for business success.