STAGE GATE CONTROL PROCESS AND ITS CREATIVE ADAPTATION TO THE MANAGEMENT OF INNOVATIONS IN GENERIC PHARMACEUTICAL BUSINESS

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Abstract

Not only innovations but also their management should be considered crucial for future company success. Many a company lost its competitive edge or even fell into oblivion as a consequence of lagging behind competitors in timely launch of innovative product. Only then can companies win their competitive advantage when innovation process adheres to set of proven managerial principles. If not managed properly, innovation process gets stuck in early stages and doesn´t bring benefits expected. To facilitate and speed up innovation process, companies have recourse to formalized and purposefully established procedures which ensure required effectiveness of the process. In general this process involves identification of innovations, their preliminary screening and evaluation from various perspectives as well as transformation of ideas into product or service. Innovation process is then completed by a final innovation launch. Stage Gate Control Process (SGCP) represents generally recognized framework for effective management of innovation processes. In some cases companies can adapt this generalized concept to fit in with company´s purposes. Such a tailor-made adaptation of Stage Gate Control Process is exemplified by the case taken from generic pharmaceutical industry. Establishment of formalized innovation management system at Cayman Pharma not only accelerated new products development and shortened time to launch but also multiplied company value in consequent acquisition process.

Key words: Stage Gate Process, innovation, pharmaceutical

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Introduction

As a one of basic strategic goal is usually considered winning competitive advantage which enables company to outplay competitors and generate value for shareholders. Any company has to possess key competencies which are underlying factors for generating competitive advantage. These competences should be unique and hardly to imitate. One of the most significant competences is company ability to innovate. For the innovation to be customer value generating it is essential to be properly designed and timely launched. In order to meet these demands, company has to establish functional and effective management of innovation

activities. Notwithstanding possible variability of innovations there is an idea that a sort of formalized process can be conducive to effective management of innovation activities. Once such a process is put into effect then the company may proceed in consonance with prescribed and properly defined steps and bring innovation project to the end in expected time and with relatively low costs. The term innovations or innovations management is closely combined with the concept of innovative company. Both the former and the latter concept are properly addressed in this paper.

1 Innovative company as a new paradigm

Even if the term innovative company has become a buzzword over past several years, not every company which declares itself as *Innovative Company* deserves this designation. To begin with, it is inevitable to raise a question what innovative company actually looks like and what are typical features of innovative company. It´s not far from true, that innovative company is such a company that systematically uses innovation for achieving competitive advantage.

Innovative company is determined to develop corporate culture which establishes grounds for generation of innovative ideas and gives priority to the most brilliant ones (Galbraith, 1999). So that innovation ideas can be fructified, innovative company should establish supportive organizational structure, correctly set processes and fairly set reward system. It must be supported by "soft" managerial practices as selection of exceptional people who are capable to commercialize ideas and thus help generate value out of them. The concept of innovations pushes through the idea, that innovation is everybody's job and therefore innovation is not an exclusive task of R&D department (Dyer, et al., 2011; Johnson, 2012).

Establishing innovation culture requires getting focused on things that make the company successful on the existing market. Furthermore the company should diversify its activities in areas, where the company looks for the next opportunities. The company should stay partly conservative to retain existing best-practices and yet be willing to take risks in new business opportunities.

Innovative companies have in common several characteristics (Pitra, 2006).

- They set up a clear goals and long-term strategy.
- They create corporate culture which supports entrepreneurial mindset of their employees. Such a culture enables stimulating ideas as well as their critical evaluation, realistic execution, and encourages employees to take risk of failure.

- They interpret accidental failure as a valuable experience and employees are encouraged to confessing their mistakes without any punishment and support sharing this lesson with others.
- They are able to act flexibly when facing new challenges. On top of that they bear in mind necessity to meet needs of future consumers and offer them new products of highest quality.

2. Management of innovation - Stage Gate Control Process

One of the most popular approaches to management of innovations represents Stage Gate Control Process (SGCP). In general SGCP is a conceptual and operational road map which enables passing a new product project from the very idea to a final launch. SGCP typically consolidates tasks and decisions into a bundle of activities so called *stage*. Innovation effort can be then broken down into distinct stages to make project supervision more illustrative and effective. Passing on the innovation from one stage to another is contingent upon meeting criteria and the approval of management gates (so called gate keeping).

In practice project teams have to complete predefined set of respective cross-functional activities in each stage prior to obtaining gatekeeper approval to proceed with the next stage of product development. This formalized process facilitates passing innovation process through stages, sets down key milestones and takes into account critical success factors. When the stage is completed, the project is critically reviewed against the set of metrics which qualify the project for moving to the next stage. It is so called gate control. Level of rigidity of the gate control is based on the type of innovation. Radical innovations require a bit more relaxed stage assessment as compared to incremental innovations (Schmidt, 2009).

Roberts (2007) suggested a set of generic stages as follows:

- **Recognition of opportunity.** In this stage, the person concerned looks for recognition of technical feasibility and/or market opportunity, actively search for ideas and inventions.
- **Idea formation.** In this stage the very idea is turned into a model. Idea generation phase includes exploration of various technologies and their possible convergence to tentative application. This phase ends up with the first formal review, where technical feasibility and commercial viability of the innovation process are assessed. Early phases of the innovation system (opportunity recognition and idea formation) should not include strict goals as for timing and deadlines. Time is not usually considered to be crucial in the phase of concept formation and planning. The quality of the output is

rather superior to timing (Hedlund, 1995). Heising (2011) even came to conclusion that so called "*ideation*" is a crucial factor for the next success of the portfolio of innovative products.

- **Problem solving.** In this stage, validation of the model should be conducted. In the problem solving stage, formalization of the concept is carried out and quantitative indicators for measurement of forecast demand are used. Similarly product and project costs are estimated and likewise pricing is set. Consequently budget for the next steps is allocated (Chiesa et al., 2009).
- **Prototype solution.** In this stage, the respective person finds a technical solution to the problem and prepares it for implementation.
- **Utilization of a solution.** Solution discovered is turned into applicable solution, for example transfer of development projects to product manufacturing. In the development stage, the project becomes more focused on application of the technology, and in particular on the development of an early prototype, which is usually an "early bird" of any technical innovation. All the attributes of innovation are being continuously refined to fine-tuned technology until they reach a stable point. At the end of this development phase the first production series may be launched and it is possible to let customers test the product, especially (but not exclusively) through the involvement of lead users.
- **Commercial development.** Innovative initiative embodied in the product is put on market. At the beginning of commercialization stage, development moves to the production and commercialization of the product. Through a strong involvement of marketing and sales units customer needs and preferences are clearly examined and taken into consideration. It may proceed both through performing customer trials and development of marketing plans. Activities performed then result in more refined prototypes (Chiesa et al., 2009). The commercialization phase of the project apparently poses the biggest difficulties (Hedlund et al., 1995). It is worth mentioning that from 35 to 60 % projects that reached the launch phase are successful only (Killen et al., 2008). As the main issue of the commercialization phase is considered the non-acceptance of the outcome by a final market. The failure rate of new launches may be mitigated by stricter use of tight control, tougher financial criteria for resource use accompanied by a formal evaluation of these resources and last but not least by higher marketing involvement (Roberts, 2007).

Some stages can be merged together. There is no recommendation as for the exact number of stages. Number of stages is derived from the typology of innovation. There exists a simplistic rule which might be applicable to real processes. In general the higher investment into the innovation and the lower project risk acceptance is assumed then the higher number of stages should be involved in the project. On the other hand, the more radical the innovation project is, the lower number of stages is required. For the radical innovation projects, three stages only are recommended (Chiesa et al., 2009).

2.2 Management of innovation activities in generic drug business

Generic pharmaceutical business is based on principle, that companies are focused on commercialization of products, for which patent protection has already expired. Such a protection can ensure patent holder to have a priority in using product or process for the next 20 years and such a patent protection can secure long lasting competitive advantage. No sooner are other companies allowed to put the same product under its brand name on the market then the patent expires. Development of unique and up to present unknown products or procedures or incidentally known products with significantly different utility value is enormously demanding and in the last resort very costly. Huge and global multinational companies only can afford to tackle development of innovative pharmaceutical products while the others shall proceed with generic drugs development. Development of generic drugs by no means signifies that the company is non-innovative. The company may develop its own unique route to generic drug which can be entirely or partly protected by patents. Then the competitors are pushed to look for alternative technologies which wouldn´t be in conflict with existing patent. It illustrates how important is the innovation effort in generic pharmaceutical business, which gives a chance even to so called "fast-second" to capture at least a part of generic drug market. Notwithstanding lower development costs the development of these types of products is also very demanding and time consuming. The trigger point for this generic drugs development is the expiration of patent protection which is usually supported by customer demand to have this product available for the distribution. Another impetus for development of generic drugs is usually results of a basic research which prove that the company is able to cope with technology that assures that generic copy of the drug is identical with the original. Due to complexness and demandingness of innovations in generic business, it is necessary to regard new generic product innovation combined with consecutive product launch as a breakthrough or radical innovation. Company ability to tackle this type of

innovations is ranked among key competences which create basis for winning competitive edge over market rivals.

A bit curious situation comes to pass when the company in generic pharmaceutical sector is determined to implement incremental innovation. Even if the very innovation is relatively cheap and simple, the regulatory framework, within which this business operates, imposes complex regulatory restrictions on the execution of any change. It is not exceptional that these impositions almost prevent company from the execution of incremental innovation process. As far as approaches to management of innovations in pharmaceutical business are concerned, over decades the managements of radical and incremental innovations in pharmaceutical industry have been believed to follow different principles. Nevertheless recent revelation of Cardinal (2001) proved that the management of radical and incremental innovations in pharmaceutical business is more similar than previously thought.

2.3 Cayman Pharma s.r.o. as an example of innovative company

Cayman Pharma s.r.o. is the mid-size pharmaceutical company which is focused on the development, production and sales of active pharmaceutical ingredients. Company is engaged in hormonal products development. Both development and a final launch of this sort of products belong to extremely demanding activities. Development of a new product thus requires exploration of multistep technology, its optimization and validation. In order to minimize failures, the company established formalized innovations management process, which bears resemblance to SGCP.

Stage 0 - discovery: Activities are oriented on revelation of opportunities and generation of new ideas about the product. Process of innovation is initiated by collecting ideas, which may originate both inside and outside the company. Ideas generators are usually R&D or marketing people. The output of this stage is critical assessment of ideas from various points of view like environmental impact of technology, accessibility of key sources, preliminary technical feasibility etc. If the results substantiate further proceeding with the idea, then the topic is moved to the next stage where it is subjected to preliminary laboratory examination. The gatekeeper in this stage is an expert panel which is composed of R&D Managers and specialists, Quality Assurance Managers and Technical Managers.

Stage 1 – scoping and laboratory exploration: A comprehensive assessment of technical and financial benefits of the project and its market prospects is performed. This stage usually works with variant and scenario approaches. This critical stage must prove that the technology projected is feasible from technical point of view. In addition to irrevocable confirmation that

the company is capable to accomplish technological part of the project, it is necessary to examine if the technology provides actually generic copy of original drug. To avoid potential intellectual property conflicts, preliminary laboratory development should take into consideration only those technologies which are apparently patent free. The output of this stage is Opportunity Study which shall be approved by the gatekeepers top Management Team and Managing Director.

Stage 2 - development: Development plans are transformed into concrete deliverables. Plans are broken down into several phases, each of them being substantiated by comparison with predefined milestones. Technological development and engineering is performed in its full complexity including scale-up, technology placement, ancillary operation ensurance and pilot production tests. In addition to technological development, marketing, logistic, quality assurance, operating and especially financial plans are elaborated. Finally the test plans for the next stage are defined. The output of this stage is Feasibility Study which shall be approved by the gatekeeper Board of Directors.

Stage 3 - testing and validation: Testing and validation of processes are activities which are ranked among the most important ones. The purpose of this stage is to perform validation of the entire project including process validation and testing methodology validation. Both aforementioned types of validation are prerequisites for getting final approval from regulatory authorities. On top of that customer acceptance of the product and the economics of the project are subject to final verification. R&D and Quality assurance Directors have to put their fingers on consonance of project parameters with publically posted regulatory standards. These standards are addressed in Regulatory Bodies' guidelines (typically SUKL[1] and FDA[2]) and various Pharmacopoeias (European, US, Japanese Pharmacopoeia). The output of this stage is a validation report. Gatekeepers are R&D and Quality Assurance Directors.

Stage 4 - final audits of the process: Final audits of the process are critical milestones which qualify the process for commercialization. Successful passing these audits is a precondition for product commercialization; otherwise the company is not allowed to put the product on the market. The audits are focused on several key topics like:

- **Health and safety** – audit is performed by Regional Hygienic Station which has to confirm that new technology is safe.
- **Environmental compliance** – technology from environmental point of view shall comply with 2008/01/ES or its Czech equivalent 76/2002 Sb. When implementing

[1] State Institut for Drug Control in Czech Republic
[2] Food and Drug Administration in USA

new technology, companies have to submit updated version of so called *Integrated Prevention and Pollution Control (IPPC).* Approval is granted by a Regional Office which judges whether Best Available Technology (BAT) was actually used and environmental pollution is within prescribed limits.

- **Compliance with Quality Assurance Standards** – this is the most challenging part of the approval process. Auditors examine whether there is a compliance of company Quality Assurance System with codified standards as well as principles of Good Manufacturing Practice (GMP) were actually applied on new technology at full scope. If the company fails to meet GMP standards, then the company is prevented from the production of pharmaceuticals. Gatekeepers are both internal and external auditing bodies like internal company audit, SUKL, FDA, Regional Hygienic Station or Regional Office. Internal mangers are responsible for company preparedness for final "sharp" audit while external regulatory body auditors have an integral authority to grant a final approval which enables the company to market the product.
- **Stage 5 –Launch of innovative product:** Any pharmaceutical product has to be registered by customers who eventually take charge of the registration of the product with respective national health authorities. Therefore it is necessary to provide customers with full support. To speed up registration process, it is necessary to provide customers with maximum available data so that the customer may avoid redundant work. Registration process, depending of demandingness of registration authorities, is sometimes very protracted. Unfortunately unless registration process is completed commercial production cannot be started. Therefore it is an intention of the producer to be conducive to the customer and it is of advantage if both make joint effort to commercialize the product in shortest possible time. From the legal point of view it is necessary to execute all the sales contracts, arrange for logistics etc. Gatekeepers are internal company managers who are held responsible for smooth cooperation with the customer as well as for putting all the technicalities into effect.

Cayman Pharma, while implementing its version of SGCP, became one of leading companies in the branch. It enabled the company to reinforce its competitive position in terms of capturing larger market share for new products and approaching new customers who were in the want of an innovative product. Due to effective management of innovations the company was able to expand its product portfolio and thus to diversify company business. It was almost immediately appreciated by customers who considered the company to be more stable reliable as a business partner. Even before reaping profit

from new products potential investors started to boost bids for company stake. The company was finally sold to a new investor who recognized hidden potential of effective management of innovations. Final bid as well as execution price more than quadrupled company book value. This example shows how effective innovation management process may have an impact on company value through reinforcing competitive position.

Conclusion

Formalized and properly structured methodology of innovation processes may become one of the key aspects of winning competitive advantage. Companies strive to outplay competitors and therefore they are looking for tools which help them both speed up innovation process and find such attributes of innovation which generate higher value for customers. Companies can boost their competitive position through capturing larger market share for innovative products, grabbing quite new business with innovative products and diversification of company´s product portfolio.

One of the innovation management methodologies, which enjoys general acceptance among professional is Stage Gate Control Process (SGCP). Notwithstanding prevalent use of SGCP by established companies which are generally focused on large scope innovation projects, even mid size and small companies can use formalized innovation management methodology. Due to small scope projects or diversity of innovations they have to adjust formalized process to their particular conditions. These companies may address all company particularities so that the process would be lead at optimum level. Using formalized innovation process which is derived from SGCP is exemplified by Cayman Pharma Company. Not only does the company benefit from using derivation of SGCP but the company also attracted attention of investors who properly assessed innovation potential as well as sophisticated management of innovation processes and bid for the company more than four times above book value. The company thus succeeded in getting competitive edge over rivals who was then turned into significant increase in company value.

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