

Innovative Business Models in the Pharmaceutical Industry: A Case on Exploiting Value Networks to Stay Competitive

Regular Paper

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Abstract The search to find a more efficient and effective way of managing processes, while maintaining the integrity of research and manufacturing activities, has led pharmaceutical firms, and other actors of the renewed pharmaceutical supply chain, to modify their own business models. This article aims to emphasize this dimension, highlighting, via the observation of a network of firms operating at different stages of the pharmaceutical supply chain, how business models have succeeded in complementing each other and in originating a value creation network.

Keywords Business Models, Value Networks, Innovation, Pharmaceutical Industry, Contract Manufacturing Organizations

1. Introduction

In light of the challenges that the pharmaceutical industry is experiencing in mature markets, pharmaceutical and

biotechnological firms are restructuring their supply chains with the aim of reducing costs and maximizing productivity.

The consolidation of the industry, resulting from the wave of mergers and acquisitions that has interested the pharmaceutical and biotechnological world, has led many plants to become redundant; many players have productive capacities that exceed the actual demand. Consequently, several dedicated productive structures – for example patent-protected drugs – are losing their sheen as branded drugs lose their patent exclusivity and face increasing competition from generics.

So far, literature has widely analysed the pharmaceutical and biotechnology industry under a number of different perspectives, such as the resource-based view [1-2], the knowledge-based view [3-5], strategic groups formation [6-8], innovation propensity and firm profitability (recent studies have empirically tested the influence of a group of innovation related variables on company performance,

with findings suggesting a positive relationship between the two) [9-12], inter-organizational collaboration and learning effects [13-16], vertical integration and collaborative agreements [3-4], outsourcing [17-19], alliance formation [20] and network perspectives [13-15, 21]. The pharmaceutical industry has, indeed, seen a deep transformation in recent years; in terms of the geographical concentration of the R&D and commercial activities, increased regulatory controls and technological complexity and expanding disease targets and cost containment policies. The life sciences and biotechnology have transformed the prospects and processes of drug discovery together with their development, while the rise of healthcare and prescription drugs spending has induced cost containment policies. Combined, these factors have affected the structure of the demand in all the major national markets. Stringent requirements for the approval of new drugs, together with the orientation of research towards increasingly complex pathologies, have implied larger, more costly and internationally based R&D activities, among others [22].

The rise of the development costs is driving the search to find a more efficient and effective way of managing processes, while maintaining the integrity of research [23] and manufacturing activities. Pharmaceutical firms, and other actors of the renewed pharma value chain, have replied by modifying their own business models. A business model “describes the rationale of how an organization creates, delivers and captures value [24]”, or in other words draws “stories that explain how enterprises work [25]”. Despite the rising importance of the business model framework, little attention has been devoted to the role played by crises in re-shaping its configuration. Furthermore, little attention has been paid to the way through which companies may survive the crisis by letting their business models complement each other in a network; in fact, once in there, firms will eventually be able to compete successfully within the changed business ecosystem.

This article aims to emphasize this dimension, highlighting how business models have succeeded in complementing each other and in originating a value creation network. This is done through the observation of a network of firms operating at different stages of the pharmaceutical value chain. We will thus address the following research question: how can business models complement each other in a value network and survive an industry crisis?

It becomes crucial to consider the effects of exogenous shocks within the framework of firms’ business models as, even if often unpredictable, crises inevitably play a key role in the global business ecosystem. Hence, the purpose of this article is to demonstrate that the solution for

pharmaceutical firms to survive in a new arena of competition, will be to let their business models complement each other within a network, where the missing piece for one firm may be compensated by another firm and vice versa.

2. A brand-new chain; innovative business models for pharmaceutical firms

At a global level, big pharmaceutical firms execute activities that are correlated to different stages of the chain, particularly regarding core products, protected by intellectual property. The production and distribution of their own products is related to the historical vertical integration of the pharmaceutical firms that leads them to an underutilization of their resources and to an increase in their costs. These factors have nurtured the choice, from several big firms, to close their plants and outsource part of their production to third parties, namely Contract Manufacturing Organizations (CMOs). Figure 1 highlights how, at the different stages, a renewed multi-player pharmaceutical supply chain has called for specialized actors to support integrated firms offering specialized services. This drives the general trend of the industry to outsource to specialized suppliers activities that are complementary to research, like the scouting of potential molecules, products for in-licensing strategies and activities related to development and trial, through the outsourcing of the trials’ coordination to clinical trial service firms. Within this new chain, in terms of production, the tendency of pharmaceutical firms is to outsource to CMOs, combining them with services as packaging and formulation.

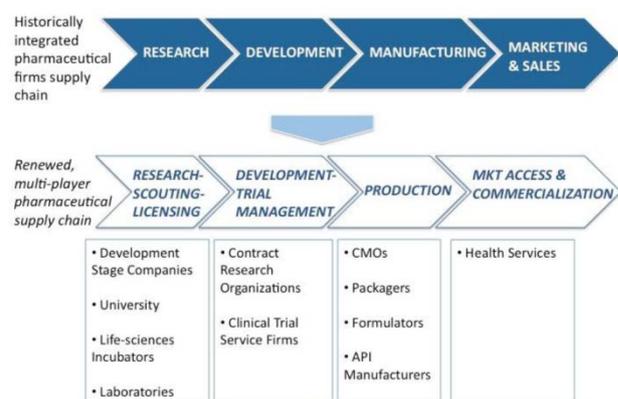


Figure 1. A brand new supply chain. Source: adapted from IMAP, 2012 [26]

Among the actors in the pharmaceutical value chain, the role of CMOs has been continuously growing. The phenomenon of plant-production restructuring and outsourcing of excess capacity is mainly evident in mature markets, including the US and European countries, where a divestiture of productive assets has taken place since 2006-2007.

From the point of view of big groups, the divestiture of productive plants to CMOs is an important effect of the reduced production. It represents a strategic action that allows firms to withdraw from underused plants, recover investments and at the same time achieve an increased flexibility in production. A common divestment strategy for the big pharmaceutical firms seems to be, in fact, the transfer to third parties of production plants and, contextually, the signing of medium-long term supply contracts for API and pharmaceutical specialties produced in the same plants. In this way, these companies ensure quality and secured supply while offering third parties an initial deposit and then adding further contracts. Outsourced production involves both active pharmaceutical ingredients, in which several suppliers with unique differences, in terms of technological platforms and productive capacities, and finished goods, are active. Furthermore, to face the needs of a highly competitive market, CMOs also aim at providing complementary and integrated services, like formula development, packaging and distribution. In fact, where production is integrated, there is lower risk of contamination, and thus a decrease in the cost of finished goods.

Relying on CMOs allows traditional pharmaceutical firms to foster efficiency on the production side, to reduce time-to-market and, once demand is decreasing, to flexibly adapt to their productive capacity without the need to operate in under-efficiency conditions and to face further investments in productive assets. On the other hand, for the CMOs acquiring such facilities, it becomes possible to create investments in line with their strategic needs and, while optimizing the usage of internal resources and the outsourcing of non-core activities from big-groups, to acquire new production-related competences.

The interest towards European sites is increasing both from US firms and from Asian acquirers, who are looking for assets placed in Western markets in order to enlarge their technological basis to 'scale up' the drug production's value chain. Competition from Asian firms is jeopardizing European firms, both because of the increasing quality of the products offered and of the lower prices. If CMOs are able to provide a bundle of services with high added value, ranging from an advanced formula to packaging, while granting low contamination, reduced costs and increased efficiency, then their relationship with acquirers could become stronger in a *win-win* strategic perspective for both parties, with positive returns on the industry and on the firms that provide complementary and ancillary products.

The possibility of benefitting from such a specialized range of suppliers for different stages of the value chain has led pharmaceutical companies to move towards new

business models. In these models the strategic choices related to the organization of the supply chain can be framed as the basis of the competitive advantage that firms may gain in differentiating their offerings.

In this context of new chain fragmentation, it is possible to identify different business models for pharmaceutical firms, drawing on different levels of externalization extension and on different types of activities that may be outsourced or developed through the collaboration of external actors. While analysing these collaboration patterns in the light of transaction costs theory is not the scope of this work, it is important to recall the traditional transaction costs economics theory [27-29]. In this theory, inter-organizational agreements are intended as intermediate forms of transactions between market and hierarchy, that may enhance competitive position through market power or efficiency [29] and reduce the production and transaction costs for the fier involved [30]. In light of this, drawing on the idea of "virtual manufacturer" [31] firms shows that they operate as coordinators standing very close to the "market" edge of the continuum between hierarchy and market. Virtual manufacturer firms considerably externalize the supply chain, from production to distribution, overcoming the idea of a "strategic outsourcing", that aims to restrictions of the ties of rigidity or capacity, with a deliberate strategy that requires the construction of an integrated network of supply partners, acting as a coordinator of the entire process. To date, this represents a niche strategy, pursued by small specialized firms, that favours a basis of flexible costs with minor risks associated with the investments and an open access to new technologies and competences. Within the continuum, firms may decide to operate supply chains that are able to cover both production and distribution stages, exploiting a *portfolio of suppliers* to provide innovative healthcare services. In order to pursue these strategies, a significant restructuring of the chain is required, with a remarkable investment in the generation of internal competences and of relationships with external actors. To satisfy the request for innovative services, these firms need to be endowed with a network of reliable and flexible suppliers. The differentiation of the offering is made possible thanks to the supply of integrated services. Finally, firms may decide to exploit the network of partners to enter the market as low-cost producers, commercializing products at convenient prices. This will require a clear comprehension of the operative costs, in a way to allocate them precisely between the different products and services in their portfolios.

As mentioned, the level of network collaboration needed by the virtual manufacturer is intense and requires strong coordination competences to manage relationships with a large pool of specialized suppliers. A service innovator

firm, in order to offer the market a product equipped with advanced services, will need organizational and relational competences. Turning to external producers or distributors seems to be instead very limited for traditional models, as these firms have to reach very high levels of internal efficiency.

Together with the traditional pharmaceutical value chain, it is important to notice there are areas that are tangent to chemical-pharmaceutical development, such as biotechnologies, that integrate research, enlarging commercial areas and increasing the value added to their final products. The impact of biotechnologies is increasingly rising, and integrates the pharmaceutical value chain in its different stages. The chain, hitherto intended as a value chain, involves the activities executed by pharmaceutical firms to provide value for their clients. The pharmaceutical value chain begins with the gathering of assets to finance its R&D and ends up with the commercialization and sale of the products derived, usually with the setting of a premium price. Opposed to this value chain is the value chain of the actor paying (mainly national healthcare systems or mutual insurances) that creates value for its customers while providing them with the access to medical care in a regime of quality and security. Synergistic to both goals (of pharmaceuticals firms and of paying customers) is the complementary sector that deals with ensuring the quality and security of the process. The analyses of impact on health and on environment and the related risks are, in fact, developed by a spectrum of heterogeneous actors, ranging from firms themselves to societies specialized in the process innovation. These entities facilitate and improve control in the waste treatment and in the personnel training throughout the development and implementation of methodologies and technologies. Finally, we add the societies specialized in ICT that support crosswise the industry along its value chain.

3. How networks reply to new strategic needs

The pharmaceutical industry still plays a primary role in the Italian scenario, showing a value of production in 2013 of €27.6 billion, a 7% increase from 2012, with exports leading the entire sector (reaching 71% of the total value of production in 2013); however, it lacks the investments in innovation needed to drive the competitiveness of pharmaceutical firms in the long-run (in 2013 R&D expenses accounted for €1.220 billion, a 0.8% decrease from 2012) [32]. The recent crisis has in fact shifted the competitive arena for pharmaceutical firms. Changes in the business models seem to have roots that are more profound, attributable to the maturity of the market, shrinking productivity, the decrease in research outputs and significant changes in the global competitive environment. However, for firms within the industry in

the US and EU regions, the growth gap between the domestic markets and the international ones remains deep, and forces them to review their strategic paradigms, restructuring their value chains, both with a qualitative upgrade in the offering and by inserting themselves in increasingly global chains.

The industry is far from running out of its entrepreneurial cycle, but is aware of the growing challenges deriving from the presence in increasingly competitive markets. Consequently, it becomes necessary to search for solutions that enable the strengthening of their business models. Companies are, therefore, seeking the collaboration of specialized players. Established and emerging life science clusters favour the sharing of know-how, competences and resources of excellence. These interorganizational collaborations can be seen both from a resource based and knowledge based perspective. The first is in respect to the complementarities in firms' resources, as the firm is a bundle of resources and the most common motive for collaborative relations is the interdependence in resources. This means that firms form alliances with other firms because they are not self-sufficient, and they cope with the arising uncertainty by restructuring their exchange relationships, accessing resources held by partners [33-34]. In the latter view, collaboration is seen as a means to learn or absorb critical skills or capabilities from alliance partners. External collaboration is, in this view, complementary to internal capabilities in the sense that they facilitate the exploitation of existing knowledge [35]. Collaboration between firms not only enhances learning about new developments, but also strengthens internal competencies and thus the locus of innovation is connected to networks of learning [13].

Literature on motives behind cooperation and inter-organizational agreements leads to the explanation of the network genesis processes: industry dynamics and market uncertainty drive the search for technological, as well as market, opportunities which affect strategic choices [36]. The coordination among different subjects can enhance the contribution of each actor through its own competences and technological assets [13]. Moreover, collaboration reduces the exposure of the single actor not only to market and technological uncertainty, but also to the associated risks and opportunism [37]; risk and uncertainty proneness (or aversion) are influenced by the network of actors and the environment surrounding the firm. Networks have also been identified as loci of learning [13], in which routines are specifically devoted to interorganizational knowledge transfers. According to a knowledge-based perspective, networks allow the leveraging of network knowledge and the generation of competitive advantages based on superior innovation [38].

The evolution towards strategic networks must be guaranteed by an environment that ensures solidity, depth and certainty in the relations. Extensive relations among partners enhance trust, as shared norms of behaviour are established (a dense network activates mechanisms of information on opportunistic behaviour and threats of sanctions that retain firms from malfeasance). Moreover, being actors embedded within relational, institutional and cultural contexts, close ties increase the likelihood of fine-grained information transfers and joint problem-solving arrangements [39]. While conducting joint projects, firms combine their skills and share their knowledge [40] as common partners tend to encourage cooperation, reciprocity and sharing [39]. Trust is essential to foster a resource-sharing mechanism that is less likely to take place in the presence of structural holes; the higher the trust among actors, the lower the uncertainty about resources exchanges.

4. Case study

We have analysed the case of four Italian firms, located in the pharmaceutical district around Latina (Rome) and active at different stages of the pharmaceutical supply chain. We conducted semi-structured interviews [41], mainly related to the nature of their aggregation, their future purposes, and how this aggregation would have been able to strategically revitalize their business models and their area while facing the increasingly global competition. We went in depth in trying to induce how they believe their new competitive model, their network, could step from an operational level to embrace more strategic goals, while pooling resources and sharing common projects. To triangulate our results [42], we then collected quantitative data obtained from secondary sources for these four companies; in this way we aimed at an in-depth exploration of the insights that came out from our interviews and, thus, from our qualitative method. Furthermore, we complemented the findings generated from the interviews with the four firms by conducting three expert interviews.

Once the data was collected, we coded the interviews and categorized concepts that pertained to the same phenomenon [43]; then, in order to present in a rigorous approach of our coding process, we made use of the Gioia methodology, building a data structure that entailed first order concepts on one hand, which are “at the level of the informant terms and codes [44]” and, on the other, second order concepts, that are “at a more abstract level [44]”. From the latter, we derived some aggregate dimensions to serve as the basis to animate the otherwise static concepts that emerged from the interviews, eventually developing a grounded theory model.

We then proceeded by taking a sample of other companies (that are not yet part of the network) within the pharmaceutical district of Latina, all of which are representative of different stages of the supply chain. To provide a complete overview of the industry, we covered all the related activities, from the production of raw materials for the chemical and pharmaceutical industry, to the drug discovery and research services, from the distribution and sale, to firms that provide consulting services related to technological innovation. We included both small-medium and large firms in the sample in order to grant a heterogeneity of perspectives related to the issues investigated. Thus, we were able to highlight both the differentials in their business models towards their approach to crises and their willingness to take an active part in a network as an answer to the crisis that they experienced as part of the district. For these firms, we conducted semi-standardized interviews structured with open-ended questions regarding their business models, the future technological trajectories of the specific stage of the supply chain, and their perspectives about the involvement within a network that could revitalize their area and that could give an impulse to the industry as a whole. As for the other interviews, we coded them by using the Gioia methodology again and then we pooled these insights with the ones gained through the interviews with the four firms within the network to shed brighter light on our grounded theory. Findings of the interviews allowed us to trace what follows: the four Italian firms located in the pharmaceutical district around Latina have decided to establish a network based on the “Business network contracts” form (Contratti di rete di impresa) that has, since 2009, recognized partnering on specific strategic goals and mutual activities with full legal effect. The goal of this specific type of contract is to increase innovative capacity and competitiveness on the market for the firms that decide to partner. It becomes a key element to support the construction of strategic networks, providing a basis for the formalization of relations, rights, duties and governance of the network. The existence of a contract also identifies the network as a collective but defined subject, with effects on the bargaining power and reputation of the partners, allowing for the recovery of competitiveness.

The four companies studied include a CMO (Corden Pharma), a waste disposal company (Co.Sma.Ri), a technological machinery company (CTP Tecnologie di Processo) and a training consultancy company (Job Consult). Born as a result of entering into a network contract between these companies in order to foster the competitiveness of firms in the industry and to facilitate the economic and technological development, the network ‘Pharma Innovazione’ aims to adequately respond to the evolution that the market has experienced: that is, the need to share resources,

tangible and intangible, to put together the knowledge and heritage of the key assets to constitute a partnership able to meet the growing needs of the demand, the saturation of the supply, as well as the cracks that the crisis has opened up, by answering the challenges that the market presents with one voice. The network, through the establishment of highly synergistic actions aimed at increasing the competitiveness of the participating firms, which also generates a positive impact on other companies in the district, aims at making the entire area of the Province of Latina, former flagship of excellence in the field, the Prime Contract Manufacturing Excellence centre in Italy.

According to Pharma Innovazione, transforming the area in the Prime Contract Manufacturing Excellence centre in Italy will allow firms to create additional value for the region of Latium, shifting the focus from the traditional customer-supplier relationship to an open system of partnerships, a cluster that is able to cope effectively with the challenges that the market poses to the industry. Collaborating with the aim to develop products and services other than those currently in force, in order to offer excellence in quality standards, is a goal of vital importance for companies who want to ensure a high level of competitiveness.

In the face of a national landscape that lacks solid investments in specialized knowledge, the network Pharma Innovazione, through the collaboration agreement, has become the owner of a shared know-how. As such, it is a main player in innovative processes and in the creation of additional competitive advantage. Within the industry, Pharma Innovazione, identified today as a collective but defined entity, is a pivotal player in an economy where knowledge is a key driver of growth.

The network model allows firms to embrace open markets other than the national market, relying on partners that are not part of the Italian context, but are part of the broader global context; the network Pharma Innovazione allows its firms to face the international market in the pharmaceutical industry, seizing opportunities and overcoming challenges together. Its objectives are: (a) sharing of procurement processes and creation of a platform to buy certain product categories; (b) enhancement, sharing, conversion of the existing installation heritage; (c) streamlining of logistics; (d) reducing environmental impact and waste management; (e) streamlining of energy; (f) development of know-how and expertise of the partners and the creation of the Pole "PTEC"; (g) launch of industrial research projects; (h) development of projects that aim at defining process innovations; (i) support change thanks to tools of change management.

In order to plan, implement and optimize together the activities that the network aims to develop, it is fundamental to face three levels of intervention [45].

The first is strategic: it is essential to highlight the interactions that the network requires in order to achieve its goals, such as the degree, the style and modes of collaborations. This forms its construction, with particular reference to the definition of supply networks, production and distribution. When configuring the network, it is also necessary to identify all the actors involved in the creation of value for the customer, be they other than direct providers, such as providers of infrastructures and information. It is in fact important to determine the nodes at the basis of the network 'Pharma Innovazione', such as the relative linkages, and who among the actors is responsible to achieve them.

The second level is tactical: the focus goes from the strategic partnership to the decision of coordination that allows deployment in an integrated manner within the network flows of materials and information. However, considering that it is often complex to align interventions related to one or more business functions, the network can leverage four drivers of performance that guide the operational processes: (a) *Plants*: pivotal for the production management, define which are the places where the activities are developed. (b) *Inventory*: the driver that identifies all the raw materials and the finished goods within the network; (c) *Transportation*: involves the transfer activities within the network of inventory and raw materials (d) *Information*: is the main driver (given its influence on the other three), which collects all the data and analyses related to plants, raw materials and their modes of transportation.

The last level is the operating one, related to the planning of operations and the timely transfer of information, in order to monitor the actual status of each organizational unit.

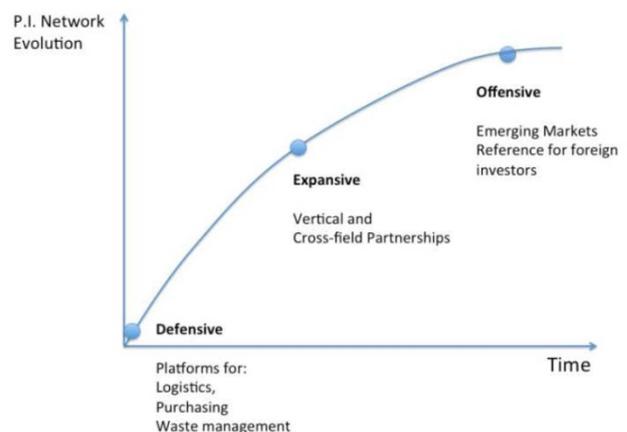


Figure 2. Pharma Innovazione (P.I.) Network Evolution

As noticeable from Figure 2, the network Pharma Innovazione, in its lifecycle, is expected to go through three stages of evolution (namely defensive, expansive and offensive). To date, the network is configured to be in a defensive phase: it is in fact mainly focused on creating platforms that enable the sharing of logistics, purchasing and waste management, in order to boost the efficiency of processes and the development not only of the pharmaceutical firms that are already part of the network, but of all the ones located in the Centre of Italy. In this phase, conceiving the network to include other actors, whose collaboration would streamline processes once granted access to a pool of shared resources that meet the needs of ensuring a proper completion of all activities foreseen by the chain, would allow firms to climb the lifecycle of the network and pass to its next stage. Such firms are therefore able to make this transition with significant resources, which enable them to realize their aspirations and developmental goals. That is why it is crucial to think about strengthening the defensive position by opening up to incorporate other partners, such as those involved in the waste disposal business: to free resources and impose security to deal with the second phase, that of expansion. In the expansive phase other agreements come into play, this time of innovation: which is when CRO partners and enterprises that are engaged in biotech would allow firms within the network respond to the wider and more articulate knowledge that the market requires in order to allow, through the use of new technologies and the full deployment of skills from different parts of the network, the development of more effective therapies. These therapies are intended to completely meet the needs of patients, and to give that boost to the innovation system that, in this area in particular, needs to be constantly enhanced. At that point, the offensive phase becomes possible for the network. This is the stage in which companies come out of the corporate boundaries to move to emerging markets and to attract the attention of foreign investors, smiting competition and continuing to pursue the high standards of excellence that have so far allowed the network to create and sustain competitive advantage. In this stage, contract manufacturing will thus represent a great opportunity especially in emerging markets, with Asian countries to constitute the main focus for large pharmaceutical companies who wish to focus their production on outsourcing.

5. Resources and competences to bet on

For firms, there seem to be two main directions in which to allocate resources and competences to ensure adequate room for growth in the future; namely, first the innovation of research and development and secondly, innovation in the approach to business (which is focused, for example, towards integration schemes and innovative

distribution, or towards solutions for the integrated management of the patient). If innovation in terms of research and development is not receiving adequate focus, neither is the one related to a different kind of approach to business, as the pharmaceutical industry is still configured to be a very traditional approach.

The Italian situation is as follows: small businesses are very fragmented and not at all focused on the development of common projects. Small and medium-sized enterprises should focus on research abroad and scouting, while trying to give life to real market specific niches, which could encompass centres of manufacturing excellence. The biotech industry has taught, among others, how the size is not vital: it is possible for small and medium-sized enterprises to play their own winning innovation game, generating competitive advantage on a global need in niche areas (e.g., rare diseases) and at the same time exploiting the commercial geographies. For large companies, the key is represented by investments in research identified through clear, concrete and achievable projects.

The right answer for success in this scenario seems to lie, in particular for small firms, in the consortium, in the cooperation or even in the network: it is pretty clear to firms within the industry how, by themselves, there is no more room for growth and development. In addition to the product innovations mentioned above, the focus must also be maintained on process innovations, in order to optimize the production and to provide end users with user-friendly interfaces. In this sense, virtual engineering projects can also be supported to accelerate the validation of new processes and the reconfiguration of existing production lines for different products.

Beyond the trajectories of innovative development at a product and process level, our interviews have shown different sets of resources and expertise needed to operate not only in the field - the resources and skills "*Needed to Play*" - but especially those needed to achieve a durable competitive advantage for firms - or resources

"*Needed to Win*". In fact the network as a whole was also analysed from the point of view of its endowment, by the four current players, of tangible, intangible, human resources and distinctive competences. Through this analysis, it was possible to understand where the network had a solid and durable garrison and had an advantage over its competitors. Furthermore, it was possible to identify in which areas the garrison is still critical, defining a gap with the competences already covered in the market by the competitors. With this aim, the resources and competences available have been identified and classified as belonging to one of the four quadrants in the matrix below (Figure 3).

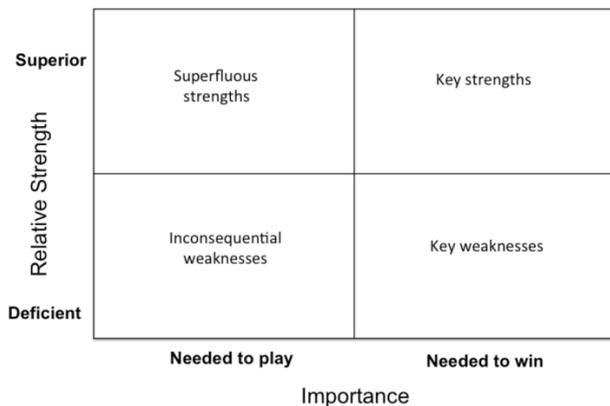


Figure 3. A framework for assessing resources and competences. Source: Grant R, 2007, [46]

For resources and competences that grant the network a superior relative strength (high garrison) and are needed to play (even if not to win) in the market, firms are endowed with superfluous strengths, which we identified to be related to inbound logistics, production, financial resources and marketing and sales. When the network has a low garrison on resources and competences that are merely needed to play the game with its competitors, it lacks what we called ‘inconsequential weaknesses’; however, once the network lacks the resources and competences that are of crucial importance in the market and are thus, needed to win (in Figure 3, the bottom right box ‘key weaknesses’, which we identified to be, among others, outbound logistics and distribution, scouting, biotechnology management and product innovation), firms will have to look for other partners to join the network and make up for the shortage of those specific resources and competences. In return, they must provide back to these partners ‘key strengths’ (i.e., quality management, time-to-market, process innovation) and with which firms in the network are already endowed.

It seems clear that the connection among the four companies has led to the creation of a portfolio of resources and competences needed to win, although the network is still recruiting new members to enhance the competitiveness of certain R&C that still appear to be weak compared to other firms and need to be further developed once their strategic importance has been recognized.

On this matter, Pharma Innovazione has been exploring the possibility of members acting on two dimensions: the first - *network width* - considering the nature of the agents - service agents or production agents, the second - *network direction* - considering the direction of partnership, located upstream or downstream of the manufacturing process. More specifically, we include in the service agents those actors involved in R&D management, quality management, waste management, energy management, ICT services providers and consumer services providers. Moreover, production agents are meant as production plants, logistics,

distributors, wholesalers and retailers. In addition, we have considered the different but closely interdependent supply chains that operate in parallel to the pharmaceutical one: namely biopharmaceuticals, medical devices and health services delivery. The integration of these chains both in the case of upstream and downstream players, once developed, can lead to a more effective planning process, allowing the evaluation and analysis of consumer demand for health needs, and to synergies in terms of cost reduction or value enhancement for the end user.

The choices regarding the potential partnerships resulting from the interplay between the two variables of *network width* and *network direction* have been synthesized in the Pharma Innovazione matrix below (Figure 4).

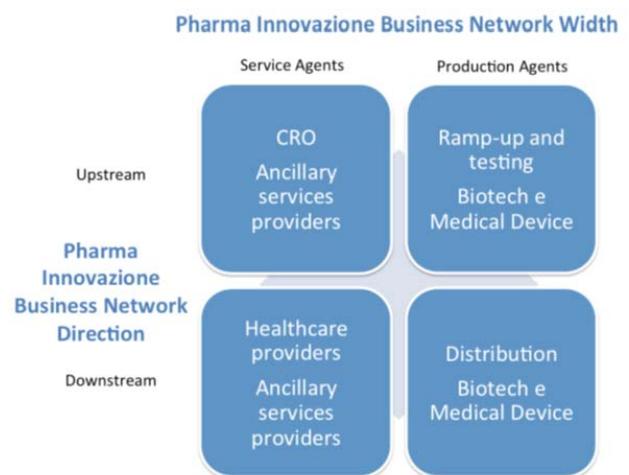


Figure 4. A framework for assessing Pharma Innovazione’s potential partnerships

More specifically, we have considered the following areas of collaboration:

1. *Upstream Service Agents.* We analysed possible expansion of the network, observing the inclusion of service agents, engaged in the upstream manufacturing process. In this sense it is possible to consider collaboration with the contract research organizations and with actors – that are indeed already represented in the network – that provide ancillary services, such as quality control, waste management and energy efficiency.
2. *Production and Downstream Service Agents.* We have included in this group collaborations with the healthcare providers for the provision of integrated services to end users. In addition, collaboration with the providers of ancillary services can still happen within the downstream structure.
3. *Upstream Production Agents.* Shifting the focus to manufacturers, and focusing on those that operate upstream of the production process, the focus is placed immediately on productive activities that support experiments and clinical trials. The focus is

also on the ramp-up and scale-up of production, certainly an area of high-quality for Italian firms as compared to competitors in other countries. In addition, opportunities arise in the integration with parallel chains of medical devices and, more importantly, with the biotech industry, certainly closer to the pharmaceutical one and with a greater growth potential.

4. *Downstream Production Agents.* We include in this area possible collaboration on the distribution side, in order to allow for a reduction of logistics costs and value creation for the end customer. In addition, collaborating with the biotech and medical device industries turns out to be feasible, and desirable, even in the early stages of production.

Pharma Innovazione, by analysing and recruiting new partners within these areas, will be able to be an agent of change, by using the network to incorporate partners that can strengthen the supply chain, but also facilitate the integration between different sectors. In this way it will be possible for firms within the network to pursue new market opportunities in related areas. Only by pursuing excellence and integration, the network will be able to modulate the supply for different types of products and markets, to manage sudden changes in demand and operate on the moderation of production costs, while maintaining a high level of attention on social responsibility and on the sustainability of excellent production processes.

6. Conclusions

As for the challenging scenario that surrounds pharmaceutical firms, there seems to be something crucial that is required to secure the long-term development of pharmaceutical companies and their industrial environment. This article aims at contributing in this direction: when a crisis hits the current business models of firms in the global business ecosystem, will not be able to generate value in the way they used to, as the environment will have dramatically changed.

Management literature has already considered the importance of business model innovation, a process that establishes firms that should not be undertaken lightly [47]: in fact, “one secret to maintain a thriving business is recognizing when it needs a fundamental change [47]”. However, our contribution will go beyond an innovation within a business model: it will entail innovation across them, where new ideas can flow as firms merge their business models and stand together as one unique player that will be able to ride the crisis, and not merely face it.

What managers can consider, thus, is to account for the potential shift in the ecosystem while letting their business models merge with the business models of other

firms and give birth to that something crucial, namely a network. A network that enables the sharing of activities linked to logistics, research and production. In fact, size alone is no longer an efficient tool to precisely portray a firm’s competitive capacity: what becomes fundamental is instead cooperation, cooperation to control all the strategic stages of the value chain.

What emerged from the interviews, once rigorously coded, is that a network becomes essential to provide a sound and sustainable answer to the emerging industry’s needs. This as it is able to generate critical mass, allowing for the development of know-how whose trace, within a model as commercial as the Italian one, is still not visible. A network will enable a decrease in costs (as for the economies of scale) and will provide firms with the strength needed to successfully enter the international market. Furthermore, entering by offering excellence can be undertaken in two phases: the introduction and launch of the product (that requires quality and flexibility in the face of the reduced relevance of costs, quality and flexibility that are unlikely to be found abroad and that represent a strength for the Italian firms), and that of production (which also ensures distinctive competences).

According to our findings, here is what pharmaceutical firms need to focus on. On a restructuring of their business models in a triangle which involves universities (laboratories - research centres), government and industry, a triangle where each is a vital side, is crucial for the overall functioning of the system: where government is no longer merely a financing body, but is rather a fundamental player to channel firms into trajectories of long-term development; where research centres are no longer deployed here and there in an area as different entities, rather gathered together to focus their efforts and funds to provide satisfying answers to the growing demands.

On the exploitation of geographical areas that are attractive for the Italian pharmaceutical firms include less developed countries where the primary needs deriving from basic diseases have not yet been covered, and where thus a business model that is different from the Western one could be successful. On an ecosystem whose centre really stands the patient and the necessity for firms to fulfil their role on a 360° basis, by being able to provide not just a drug or a product, but a service that constantly cares about its patient. On granting a continuous investment for the development of new therapeutic solutions as, albeit the importance of revolutionizing their business models, firms have to recognize that innovative products need to be provided also. Biotechnologies represent a train that Italy cannot miss. To jump on, and exploit its full potential, firms need to coordinate and cooperate within a network that is no longer national but global.

The future of the pharmaceutical industry will be focused on two types of firms: blockbuster or innovative. Where the former compete on prices, working with immense volumes, the latter focus on three principles: speed, quality and security. Furthermore, it is on these three principles that Italy may offer distinctive services, particularly regarding production: in the introduction stages, Italian firms may arrive on the market early while offering a control that is able to ensure the high quality of products.

It seems clear that the pharmaceutical industry is facing a crossroads that is substantially one of mindset: it is necessary to stop pursuing the research towards the race for a small market share, rather beginning to encourage firms to do research on those unmet medical needs and patient subcategories. R&D is important in order to be competitive in the long run, and develop the necessary added value.

Once pharmaceutical firms have learnt to bet on innovation, on the quality delivered and on the R&D, a precious heritage opens up for them: a heritage that needs to be exploited. That is why, the network needs to merge this heritage with the ones of other firms, and give rise to an excellence in all the activities of the chain, from production, to research, to services.

To date, the scenario surrounding the Italian pharmaceutical and biotechnological firms is marked by the crisis. The shortage of raising funds (that heavily penalizes the sector) is accompanied by a potential increase in costs, which makes a radical transformation necessary. Our findings agree that, to make this transformation possible, firms need to stick together, sharing their knowledge and their resources: it is no more plausible for firms to spur innovation while remaining independent. Furthermore, if innovation is a key to remaining competitive, firms can surely build innovation with a little help from their network partners.

7. References

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