Applying operational excellence beyond plants: some insights to reshape the pharmaceutical supply chain

Baroncelli, C.*, Cigolini, R., Sianesi, A.****

** Efeso Consulting, 117 Avenue Des Champs Elysées, 75008, Paris, France (carlo.baroncelli@efeso.com)*

*** Department of management, Economics and Industrial Engineering, Politecnico di Milano, Via Raffaele Lambruschini 4B, 20156 – Milano – Italy (roberto.cigolini@polimi.it, andrea.sianesi@polimi.it)*

Abstract: This paper discusses key aspects of a survey into the current objectives, practices and impacts of Operational Excellence (OpEx) in the pharmaceutical industry. OpEx has clearly established itself as an area of corporate challenge and opportunity among chief executives worldwide. The aim of the research presented here lies in discovering the "hot topics" that preoccupy senior executives and managers responsible for the supply chain and technical operations: it is important to develop a cross value chain understanding of where and how OpEx disciplines are being applied. This research study has started with two clear hypotheses. Hypothesis 1 states that the macro changes in pharma, as they affect the industry sub-sectors, have a direct impact on the nature of operational excellence thinking. Hypothesis 2 states that a generic approach to the industry sub-sectors cannot provide adequate responses. As far as hypothesis 1, results suggest that pharma companies are alert to the changes the industry is experiencing. There is also evidence of a wide range of associated actions and limited evidence of a structured and holistic response, nor is there strong evidence of instances where pharma companies take an aggressive approach to exploiting opportunities, as opposed to reacting to threats. As far as hypothesis 2, there is clear evidence from the survey that the value proposition for each sub-segment is quite different: a mix of efficiency (cost), responsiveness and time to market, with quality and compliance considerations having equal weight across each business.

Keywords: Operational excellence, Supply chain management.

1. Introduction

This paper discusses key aspects of a survey into the current objectives, practices and impacts of Operational Excellence (OpEx) in the pharmaceutical industry. OpEx has clearly established itself as an area of corporate challenge and opportunity among chief executives worldwide (see e.g. Papageorgiou et al. 2001, Mustaffa and Potter 2009, Chan and Daim 2011). Indeed, it ranked as the second most significant issue facing them (after Human Capital) in the Conference Board global CEO Challenge Study.

The aim of the research presented here lies in discovering the "hot topics" that preoccupy senior executives and managers responsible for the supply chain and technical operations: it is important to develop a cross supply chain understanding of where and how OpEx disciplines are being applied. Indeed, the industry can reduce resources used in areas that add less value and redirect these resources to more attractive opportunities.

As far as OpEx is concerned, pharma industry has historically taken a bottom-up approach, with a heavy emphasis on the plant (Shah 2004, Sousa et al. 2011, Rossetti et al. 2011). However, at least two factors tend to the focus away from manufacturing exclusively. (i) Many companies have several years of experience in OpEx, specifically in manufacturing and may be on their second or even third wave of improvement activities, so that diminishing re-turns are a distinct possibility. (ii) The trend towards high added-value specialty products means that manufacturing plays a smaller part in the overall value proposition. Given the strength of external pressures, there is a need for increased clarity around some fundamental questions, mainly related to whether improvement always resolve into a question of cost or it is also a time-related argument (Narasimhan et al. 2008, Wagnera et al. 2012, Cigolini et al. 2011, 2014). For example, the emphasis inside the plant is on reduction in cost per gram, but the real issue might be a need to accelerate response times, so that the market can be followed more closely (Godsell et al. 2006, Kristal et al. 2010, Lamberti and Pero 2011).

To this purpose, this study has started with two clear underpinning standpoints, which represent also two main research questions. (i) The macro changes in pharma, as they affect the industry sub-sectors, have a direct impact on the nature of Opx thinking and (ii) a generic (i.e. one size fits all) approach to the industry sub-sectors cannot provide adequate responses.

This study was originally aimed at gaining insight into the degree of linkage between "bottom up" OpEx initiatives - many of them historically most prevalent in the manufacturing part of the supply chain (Duray et al. 2000) - and Supply Chain considerations. More in detail, the first wave of the research presented here was intended to learn more about the specific changes the macro issues are triggering in four directions. (i) SC orientation and market approach, i.e. routes to market. (ii) Positioning of operations, particularly core competences, partnerships, outsourcing (see e.g. Graya et al. 2011). (iii) Role of product, i.e. nature of the pharma product, including service packages etc. (iv) SC management practices,

including how far OpEx-led responses are generic or sub-sector and situation-specific.

This research study has started with two clear lines of enquiry, to test two hypotheses. Hypothesis 1 states that the macro changes in pharma, as they affect the industry sub-sectors, have a direct impact on the nature of operational excellence thinking. Hypothesis 2 states that a generic approach to the industry sub-sectors cannot provide adequate responses.

The structure of the paper is as follows. Section 2 introduces the methodological pattern followed. Section 3 presents some relevant insights coming from the performed survey, while section 4 is devoted to the discussion. Finally, section 5 draws some conclusions and outlines promising avenues for future research.

2. Methodology

According to Shah (2004), there is a number of key players in the pharma industry. (i) The large, research and development-based multinationals with a global presence in branded products, both ethical and over-the-counter. They tend to have manufacturing sites in many locations. (ii) The large generic manufacturers, who produce out-of-patent ethical products and over-the-counter products. (iii) Local manufacturers that operate in their home country, producing both generic products and branded products under license or contract. (iv) Contract manufacturers, who do not have their own product portfolio, but produce either key intermediates, Active Pharma Ingredients (APIs) or even final products by providing outsourcing services to other companies. (v) Drug discovery and biotechnology companies, often start-ups with no significant manufacturing capacity.

About 30 representative companies from each segment – i.e. big, pharma, vaccines etc. – have been approached. Unfortunately, Intellectual property rights and non-disclosure agreements prevent from the possibility to publish the names of both companies and respondents, whose opinions sometimes have not been explicitly approved in advance by their employer. Anyway, Big-Pharma is considered to include manufacturers with sales exceeding $2 billion and a significant presence in the six major European markets (Deutschland, France, Italy, The Netherlands, Spain and The United Kingdom). These companies have R&D and marketing operations in at least five different therapeutic areas and have fully integrated pharmaceutical operations, including internal R&D, manufacturing, clinical, regulatory, marketing and sales.

Multiple semi-structured telephone and face-to-face interviews have been carried out with the sample group. Interviews invited responses to the following question areas: (i) understanding the company (or specific division), its position in the pharmaceutical SC and its main product flows, (ii) vision, strategy and value proposition, (iii) corporate organization model, (iv) product life-cycle management processes, (v) route to market, (vi) design and implementation of performance improvement initiatives. The semi-structured approach limited the constraints on respondents to express their views and al-lowed them to introduce novel concepts, still within an organized framework, for subsequent analysis.

Of the company profiles surveyed, branded and patented made up 65% of the respondents. Branded and unpatented accounted for 20% of the respondents, having either a strong brand but with products no longer patent protected or changing business (from branded and patented to unbranded and unpatented). Unbranded and unpatented made up less than 10% of the respondents. Interviewee sample comprised senior managers, with a strategic perspective on total supply chain and supply chain developments, as well as operational specialists

3. Insights from the survey

The survey was arranged as follows. Structured questionnaire were sent to circa 2000 senior logistics, operations and supply chain executives in various parts of the world using multiple channels. Then about 180 complete responses were analyzed to identify key themes to probe further in more than 20 structured follow-up one-to-one interviews, which helped in understanding the meanings behind some of the questionnaire responses. Finally, emerging results were discussed in workshops to capture participants' reactions

Most respondents demonstrated clear perceptions of the principal risks to their industry and their competitive position (see figure 1). Price competition is a dominant concern – 35% of respondents. Patent duration is the next most significant issue – 20% of respondents. Reimbursement is third – 8% of respondents. However, you should note the sharp drop -down to 4% - in prominence for risk areas such as Contract Manufacturing Organizations (CMOs) and Distribution Control.

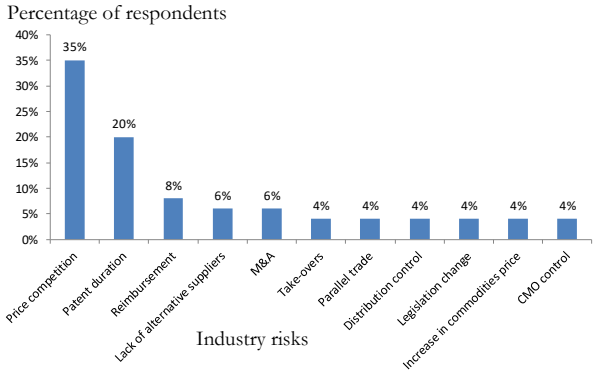

Figure 1 – Perception of the main industry risks

All respondents were asked which factors they judge as critical to their organization's long-term success in the market. They confirmed that innovation is the clear lead as a Critical Success Factor (see figure 2) followed by quality, thereby underscoring that compliance is a given. Efficiency and flexibility, and brand or product range are tied. Note the steep drop to supply chain resilience and technology – tied at 4%. A reasonable interpretation is that resilience and technology are both enablers – resilience as part of the risk management toolbox, while technology supports supply chain visibility, compliance, decision-making speed and a host of other considerations (Cigolini et al. 2004). Thus,

respondents did not see them as immediate success factors in their own right.

There is consensus that R&D is a mostly internal phase. Some 70% of respondents agree that internal R&D centers enable control of research results. A further 20% of respondents do partially outsource R&D to partner laboratories and several respondents are highly active in acquiring or in-licensing mid-to late stage candidates.

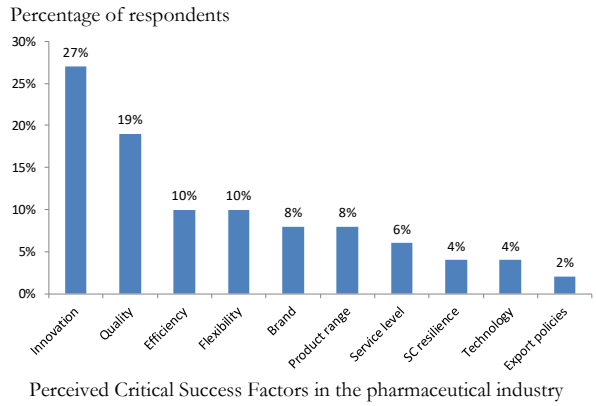

Figure 2 – Perceived success factors in the industry

There has been a decrease in life cycle; notwithstanding the fact that many industry participants would argue patent rules have not changed. Respondents also report a slowing in product range enrichment, although product lifecycle management in terms of new indications and formulations is a response to generic penetration. Finally, the survey indicated "difficulty" manifesting as R&D productivity, Risk, and cost in discovering new APIs and molecules in general (Pammolli et al. 2011, Bettiga and Ciccullo 2019).

Patents, unsurprisingly, are regarded as important vehicles to defend product R&D and process development. Manufacturing process development will take place in parallel with product development. This is generally on a small scale for clinical testing, followed by scale-up to commercial quantities. There is awareness of the need to develop new approaches, which integrate Lean thinking into process development. This is driven in particular by considerations relating to product lifecycle duration. Overly long industrial process development and/or scale-up could reduce the patented period on the market.

The need to control APIs, key component of the supply chain is evident. Some 60% of respondents produce APIs in-house; although a third will outsource if a particular production technique is required and not available internally, or because manufacturing is not considered core to the business strategy (see also Ribbinka et al. 2014, Wiengartena et al. 2014, Zhoua et al. 2014). Just 7% take a "mixed" approach, particularly related to risk management through "balanced" sourcing.

In terms of Sales and Operations Planning (S&OP), traditionally the Pharmaceutical business is regarded as unseasonal. Production volumes tend to be predictable, especially for mature patented products, while production planning at the tactical level is based on demand forecast, not on customer orders. Exceptions to this un-seasonality apply to seasonal vaccines, to specific tenders and promotions and to seasonal over-the-counter products for colds, flu, etc. Make-to-stock is the replenishment strategy currently adopted by 95% of respondents. The pharma business is highly market-oriented, driven by differentiation in regulatory mandates (Bhakooa and Choib 2013), language and packaging prescriptions. Planning and scheduling processes require high levels of integration between corporate divisions, production sites and sales geographies (Frohlich and Westbrook 2001, , Flynn et al. 2010, Patrucco et al 2020). A significant proportion of respondents operate some form of multi-level S&OP. Nearly 60% of respondents report that they have high levels of integration.

In terms of manufacturing and packaging, with few exceptions, strategic products are manufactured internally with supply risk mitigated by external backup in some cases. Production site specialization is shaped by technology and product. While growing enterprise risk management awareness is driving a degree of dual sourcing of critical products and processes, there are a significant number of respondents operating single-sourcing. There are frequent examples of plants focused on specific production stages (API, formulation, packing etc.), which are integrated into a global supply network. The packing strategy and the drivers for location (central, close to end market) are evolving but responses were not conclusive, suggesting some lack of clarity around the cost and service drivers.

In terms of manufacturing strategy, some 90% of respondents confirmed "low levels" of integration between their manufacturing and their distributors. Pharmaceutical companies do not have automatic clear visibility of sales demand data, which often has to be purchased, and rarely have access to end user consumption behavior. Yet most of them expect to continue based on low integration levels. They tend not even to acknowledge that close integration is achievable, or indeed desirable. As a result, there is sub-optimal leveraging of the opportunities afforded by better and faster information, proximity to the end user, control over diversion and other key factors. In addition, more than 70% of respondents, confirmed "low levels" of integration with suppliers and CMOs, even though their success and risk exposure is directly impacted as a result of this situation. Less than 10%confirmed "high integration". Most pharma companies are not yet open to a higher level of integration, despite the clear opportunities. As suppliers, particularly CMOs, become more structured, predictable and compliant, pharma companies can profit enormously from closer collaboration and integration.

On the other hand, pharmaceutical production respondents confirmed that process quality and compliance are key drivers, to the extent of being business critical. The focus is on efficiency and cost control. Complexity, especially in the area of packaging, is developing as a major theme, while workplace safety and human resources are areas of increasing focus (Pero et al. 2016). Production site location is driven by knowhow availability, investment opportunities, labor costs and historical factors, with

subsidies and tax advantages (asset-intensive processes) often counting as a deciding factor.

Moreover, described by one respondent as "responsible for range explosion", the packaging challenge is driven by language, legislation diversity and frequency of regulatory change. It is seen as a "step-up" factor – escalating tens of formulated products into thousands of different packed products. There is also difficulty associated with managing many small batches for low volume markets – since this brings higher production cost and risk of obsolescence (Pirovano et al. 2020).

Going further along the route to market, only 5% of respondents own and manage their distribution warehouse. There are three main distribution models: (i) wholesaler-centric, (ii) direct to pharmacy or hospital and (iii) direct-to-patient. Some 95% of respondents operate a wholesaler-centric model, while 60% have implemented direct to hospital or pharmacy distribution and less than 5% of respondents have implemented a direct to patient model.

To manage their distribution networks, the majority of pharma companies partner with pre-wholesalers, a role which is unique to healthcare. Pre-wholesalers position themselves as a single partner within a territory (usually a country) and provide a range of services including warehousing, order management, invoicing, cash collection etc. They act on behalf of the pharma companies and are responsible for the order to cash processes. They generally do not own the inventory nor the accounts receivable, but this is subject to the contract terms.

Respondents confirmed the principal objectives of their improvement programs. Cost reduction is the most important. It is imperative in order to survive "progressive margin squeeze" and to remain in the market. Then, lead time reduction drives market responsiveness, controls cash flow and beats competitors to market. Efficiency, quality, automation and control are moving targets that must be constantly reviewed and improved to drive compliance and competitive edge. Some of the programs were focused on "going back to basics" – with the emphasis on compliance and quality. However, respondents reported a degree of difficulty in some instances with actual implementation of improvement programs. There can be friction as a result of employee change resistance. Change management is a challenge and specific change management programs have a role to play, both in bedding in approaches such as Lean and helping to make sure that employees are "on side" with change rather than alienated by it.

More than 50% of respondents cite "employee suggestions" as the principal source of improvement, while about 30% cite the introduction of lean manufacturing tools and about 20% identify good practice compliance in key areas including clinical, laboratory and manufacturing. Once again, more than half of respondents confirm that they target manufacturing for improvement, with focus on technology acquisition, quality improvement, and efficiency increases. Some 35% confirm that areas such as R&D, product & process development, procurement and marketing are targets for improvement and 10% quote the supply chain as a targeted improvement area today – however, increased integration in this area is identified as an important trend for the future.

Survey respondents reported the following key macro characteristics of the supply chain management in the pharma industry: vertical integration is prevalent - in particular among larger, multinational enterprises. Direct control of R&D and API manufacturing is prevalent among branded pharma companies. Production is viewed as a critical phase, characterized by control of compliance, cost management, and access to technologies. Distribution and logistics are usually handled externally (Jarret 1998, Savage et al. 2006, Walter et al. 2012, Rossi et al. 2020), with one striking example where direct patient support was a core strategy. Availability of qualified CMOs is changing the manufacturing landscape and driving a refocus on core competencies. Outsourcing of Order to Cash (O2C) cycle is gaining momentum, together with outsourcing of some sales force functions. Generics producers focus on drug product manufacture (the vast majority purchase the API). In general, the concept of improvement is broadening in scope - and is now going beyond pure manufacturing focus.

To survive and thrive in the future pharma companies rely on growth. More than 70% of respondents confirm that merger and acquisition is the most common growth strategy, whilst less than 20% cite brand acquisition. In-licensing and acquisition of manufacturing and/or marketing rights is increasingly popular, as a means of accelerating growth. Introducing new products through purely internal development is an extremely lengthy and unpredictable process, which can also increase the level of uncertainty around the life cycle performance of current products.

Beside growth, the complexity of the pharma landscape greatly challenges executives. In the face of ever-increasing complexity, respondents cite the following attributes as crucial assets: process flexibility (facility design, lot sizes etc., organizational flexibility (multi-sourcing, facility qualification etc. and human resources flexibility (multi-skill sets).

Finally, two main relevant challenges are likely to shift the competitive paradigm in the pharma industry. First, the creation of all-treatment packages, as it redirects the focus from product orientation to delivering a whole solution and it leads to products that include drugs and medical devices, often together with complementary services (nurse, training, product supplies). A convincing 90% of respondents said this is an "interesting" direction and "a growth area". Second, the para-pharmaceutical industry, including personal care, dermo-cosmetics, supplements, nutria-ceuticals and intra-ceuticals

4. Discussion

This section is devoted to identify some OpEx-driven insights coming from the survey. The key departures include: (i) a shift from product-centricity to holistic therapy management, (ii) fostering of collaboration on innovation across the supply chain, (iii) application of lean approaches to new product and process development, (iv) reacting to and profiting from demand cycles and (v) enhancing risk management and risk mitigation. In this

scenario, respondents of the survey contributed to give birth to five main critical issues that are likely to shape the future supply chain in the pharmaceutical industry.

The first critical area is related to time-to-market. Everybody is familiar with the idea of the shorter product life cycle. However, patent legislation has not substantially contracted the patent duration, while the "protected" time available to recover investments is reducing, since the clock runs with the granting of patent, not with regulatory approval. As a result, time to approval has tended to elongate as preapproval trials become more elaborate. A significant number of respondent companies emphasized time-consuming patenting procedures. Even during patent duration, competitors look for sufficiently chemically differentiated products with similar therapeutic properties to bring to market; or those that may be able to demonstrate significant therapeutic benefit to the patient. Some companies of the sample have re-designed the organizational matrix to create a single central process owner, responsible for all time-to-market activities. Through a lean-based approach, they have redesigned their supply chain (Kumar et al. 2008) from a purely product-centric organization to holistic management of the therapy, including techniques such as early involvement of regulatory authorities.

The second critical area is related to responsiveness. Apart from a few specific exceptions, pharma is a non-seasonal sector: people fall ill on a daily basis, year round and make-to-stock manufacturing policy is a standard industry approach, with the de-coupling point usually placed downstream in the supply chain. However, some respondent companies are managing sudden and unpredictable demand peaks (Germain et al. 2008) effectively, to exploit high-margin niches such as pandemic and high vaccines inventories to protect populations. They are learning to shift the decoupling point further upstream along the chain, to speed decision making within the company and to exploit Collaborative Planning, Forecasting and Replenishment initiatives (Gree et al. 2006, Choi et al. 2012).

The third area of criticism refers to risk management. Everybody knows that industry risks are increasing. They are driven by the growing challenge of controlling a broad range of variables, or "components", together with difficulties inherent in managing specific technologies internally, as well as contamination, counterfeiting and parallel trade (Marucheck et al. 2011). In general, there is low integration with distribution partners and with contract manufacturers. However, some respondent companies have launched integrated risk management projects involving all relevant functions. They have linked their risk mitigation approach to corporate social responsibility programs. They are driving up compliance, process robustness, and working towards design for quality. In addition, they are addressing, through a range of complementary risk management approaches, the risk (batch fail through contamination, sub-optimal delivered titer/potency) presented by large, long lead-time batches of APIs. These include strategic stock holding to accommodate the loss of a production batch, pooling of production batches to deliver planned potency, and close monitoring of the process parameters to determine most appropriate time for management intervention.

The fourth critical area is in the R&D area. Everybody knows that during the R&D phase of a new API it is hard to predict pharmacological results and commercial viability. While the majority of companies keep their R&D process under total internal control, mainly in order to protect intellectual property rights, some of respondent companies are now adopting a quasi-venture capitalist R&D model. They place seed capital in promising start-ups and buy in early if the output indications are positive. They provide support in key areas, expertise, facilities, equipment, to foster development and are ready to invest if outcomes look positive. Many are now operating research partnerships. Others are highly active in the search for and evaluation of opportunities to acquire or in-license late stage candidates to complement or even replace internal developments.

The last critical area involves the route to market. It is widely understood that a direct distribution model to pharmacies and hospitals reduces risk (Jambulingam et al. 2005), is more cost-effective and more profitable. As a result, more than 90% of respondent companies in the survey sample are still managing distribution according to a wholesaler-centric model, while the direct-to-patient approach is almost non-existent. Some companies are seeking strong integration with pre-wholesalers or directly with selected wholesalers; while also considering a move to fee-for-service solutions and fourth-party logistics service providers (see lynch et al. 2000). The objectives are to minimize the number of hand-offs between manufacturer and the point of administration, to improve service, assure secure supply and manage costs.

5. Conclusion

The pharmaceutical industry is so diverse that it cannot be considered as a single, homogenous entity. It comprises businesses – entire sub-sectors – that are radically different in many important regards; including their supply proposition, target patient population, demand profile and manufacturing processes. The value model is quite different from one sub-sector to another. The major changes and pressures that act on the industry are clearly identified. Less well understood is the relationship between general trends and specific responses. Change factors do not act universally, or in completely consistent ways. There is therefore a spectrum of industry responses to a complex operational, compliance and competitor landscape.

The research presented here aims to discover more about the pharmaceutical supply chain – learning where value is created, and how it is being protected and maximized with supporting concrete data and examples where appropriate.

In particular, OpEx can be used beyond the boundaries of production plants, to respond effectively to key industry drivers. This research aims to discover how pharmaceutical companies, across the spectrum of industry sub-sectors are evolving their approach, not just to manufacturing, but to other business functions such as R&D, distribution models

and entry into new, parallel sector activity including healthcare services, to embrace the full supply chain.

By looking at the wide span of the whole pharma supply chain, it is clear that manufacturing is not the exclusive focus of change and progress. Indeed, pure manufacturing improvement, with the exception of a few specific breakthrough opportunities, is approaching the point of diminishing returns. Further, in a number of pharmaceutical sub-sectors, manufacturing has relatively low impact on overall business effectiveness, compared to other activities such as R&D or sales and distribution. This research has sought to identify where the innovations are occurring, what is driving them, and how they are being achieved. One fascinating question to explore, going forward, is whether they derive from a structured approach or they are the result of disconnected and reactive actions.

The responses to the industry survey indicate some degree of evolution in approaches to elements of the supply chain. Continuous improvement in the pharmaceutical industry will require continuous and increasingly broad engagement with new techniques and approaches, right across the chain. Whatever the outcomes, this research is aimed to develop a deeper understanding of where and how value is created, protected and grown..

To summarize, respondents cite three key areas of response to the challenges of the diverse pharma landscape. The first is restructuring, which requires organization and infrastructure transformation to attack the cost base. The second – technology – improves compliance, reduces cost and accelerates decision making. The third, OpEx, brings opportunities to re-apply learning from manufacturing programs across the extended supply chain. OpEx is among the most relevant industry responses: the prime focus of manufacturing-centric improvement programs is to reduce the cost base. However, broader supply chain initiatives are now targeting other key areas. These include lead-time and time-to-market reduction, complexity management, driving up quality and compliance and taking out costs in areas other than manufacturing.

As far as the first hypothesis is concerned, the results of this research suggest that pharma companies are alert to the changes the industry is experiencing. There is also evidence of a wide range of associated actions. In contrast, there is limited evidence of a structured and holistic response, nor is there strong evidence of instances where pharma companies take an aggressive approach to exploiting opportunities, as opposed to reacting to threats. When considering individual developments, each business segment (ethical, generic, vaccines, OTC, etc.) has specific business goals and underlying value models. It seems reasonable to conclude this indicates a need for specifically adapted supply chain solutions in each segment.

The second hypothesis proposes that a generic approach to the industry sub-sectors cannot provide a satisfactory response. There is clear evidence from the survey that the value proposition for each sub-segment is quite different: a mix of efficiency (cost), responsiveness and time to market, with quality and compliance considerations having equal weight across each business. Where pharma companies are present in multiple sub-segments, there is strong evidence that generic solutions are the norm, including processes, support tool configuration, skill sets, route-to-market, except where the businesses are managed as relatively independent entities.

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