

How the raise of a Big Data Analytics environment impacts the pharmaceutical supply chain in Europe

Marco Farinelli (marco.farinelli@polimi.it)

Department of Management, Economics and Industrial Engineering, School of Management, Politecnico di Milano, Milano, Italy

Federico Caniato

Department of Management, Economics and Industrial Engineering, School of Management, Politecnico di Milano, Milano, Italy

Abstract

Purpose To understand which contextual factors are impacting a successful Digital Innovation (DI) initiative in a complex Supply Chain (SC) and affect the achievement of benefits linked to increased data use.

Design/methodology/approach Single case study on the distribution network of pharmaceuticals in a European country.

Findings Strong governance and integrating bodies play a key role in successful DI in complex SC. IT maturity determines the type of SC benefits that can be achieved.

Relevance/contribution Identification of key contextual factors for DI in a specific environment and of key preconditions for achieving SC benefits through use of data (i.e. Big Data).

Keywords: Digital Innovation, Big Data Analytics, Supply Chain Management.

Introduction

Falsification of medicines has been on the rise since more than a decade. EU statistics report a sharp (threefold), increase of falsified medicines seized at borders starting from 2006 (2,7M articles). WHO estimates a market share of up to 1% for falsified medicines in industrialized countries, while the European Commission has estimated that approximately 1.5 million falsified packs make it as far as the legal supply chain. (European Commission 2015)

Besides the socio-economic costs of related illness (estimated at almost €1 billion a year in the EU), falsified medicines also represent a significant damage for the players of the pharma supply chain, through increased costs for recalls, loss of product trust and damage of company image. This also impacts the broader European economy, since protecting the competitiveness of the pharmaceutical sector is critical in meeting the Europe 2020 targets on qualified employment, GDP and R&D expenditure. (European Commission 2015)

In February 2016, a delegated regulation, known as EU Falsified Medicines Directive (FMD) was issued by the EU commission to cover the last segment of the supply chain, i.e. manufacturing and distribution of finished product. This new EU regulation requires

member states to implement, within 3 years, a European wide point-of-dispensing verification system, based on pack serialization. The implementation of such a system is the shared accountability of all the supply chain stakeholders: Pharmaceutical Companies, Generic manufacturers, Parallel traders, Wholesalers and Pharmacies (Retail and Hospital). (European Commission 2016/161)

While the direct benefits of EU FMD on patient health are more easily visible and paramount, the benefits of this change on the supply chain are not immediately evident to the industry, due to the high level of complexity that this innovation entails.

In fact, the underlying IT infrastructure of EU FMD is a major and mandated development across Europe and each pack will have a serial number stored and a chain of events linked to it (European Commission 2016/161), creating an evolution towards a big data environment.

From a practitioner perspective is then critically important to map out this emerging landscape, foresee the consequences of this shift and understand the impact on supply chain dynamics, to ultimately devise the right strategies for achieving competitive advantage.

From a theoretical perspective, the current literature has extensively studied the benefits of supply chain visibility deriving from the implementation of new technologies, such as labour, inventory holding, lost sales, theft costs and order cost (Lee, Özer 2007, Ustundag, Tanyas 2009). It also depicts well the evolution of supply chain informatization and identifies the dynamics and the results of technological change through the years (Strader, Lin & Shaw 1998, El Sawy et al. 1999, Gunasekaran, Ngai 2004). In fact, supply chain evolution has led to new enablers, dynamics and capabilities which then turned into the context and variables impacting supply chain visibility and its benefits.

However, the last step seems to have been neglected, the impact and benefits of big data analytics on SCM, as a further evolution of supply chain informatization, still needs to be investigated fully (Mishra, Singh 2016, Kache, Seuring 2017), while research taking big data as a case for the value of supply chain visibility is missing. At the same time, new technologies like blockchain are adding new expectations for opportunities in the supply chain scene with research being in a very early phase (Abeyratne, Monfared 2016, Zhao, Fan & Yan 2016).

Combining the industrial and academic motivations, the general objective of this study is to better understand the impacts on the supply chain of this digital innovation process in terms of its enabling factors and blockers, as well as gaining insight on what SC benefits the transformation itself and the related new data create.

The general objective can be divided in two research questions:

- RQ1: What are the most relevant contingent variables and how do they impact the digital innovation process?
- RQ2: Which benefits is digital transformation and new data availability expected to create?

To fulfil these objectives a single in-depth case study approach was adopted to investigate the impact of the ongoing EU FMD digital transformation in the distribution chain of pharmaceuticals in a smaller European market.

The answer to these questions should deepen our understanding over the impact of big data analytics on supply chains, providing a rich empirical case from the EU FMD implementation while simultaneously addressing the industry's need for a throughout mapping of the landscape together with an impact assessment.

These answers will also identify new ways to add value along the supply chain, enriching the current body of knowledge through new empirical findings and providing steer for strategy development to practitioners.

Contingency Theory and Digital Innovation literature in SCM

As mentioned in the introduction, EU FMD will create a new landscape of digitalized supply chain.

In researching the impacts of EU FMD changes on the pharmaceutical supply chain, this study takes an underlying perspective grounded in contingency theory, where organizational performance is driven by the fit with the environment, which is enabled by a high level of integration (Lawrence, Lorsch 1967).

From a contingency theory perspective, the evolving OM practices that organizations take, from time to time, are their response to the contextual variables, while their fit to the context is one of the pillars of performance (Sousa, Voss 2008).

Contingency theory is one of the most enduring theories used in OM and SCM is the most frequent topic of study in OM (Walker et al. 2015).

The relevance in taking a contingency theory view in SCM is also highlighted by (Kembro, Selviaridis & Näslund 2014), they have recognized an increased use of contingency theory “acknowledging that there is no universal solution how to approach information sharing in a supply chain”. They also suggest that the appropriate level of information sharing is determined by the supply chain context and call for more sophisticated ways to use contingency theory through in-depth case studies.

The understanding of the changing context in which the pharmaceutical supply chain operates is thus a key aspect being studied in this research.

Considering the first research question of better understanding how contingent variables impact Supply Chain reconfiguration, what should be the approach to fully understand the new landscape? What are the elements to map out and that will be shaping the supply chain dynamics as they evolve?

Already in early studies on digital supply chain, elements like process integration and activity coordination have been highlighted (Strader, Lin & Shaw 1998). (El Sawy et al. 1999) call for “organizational forms that foster collaboration and partnering”, establishing IT-Shaped Cybermediation as the capability to create value out of the knowledge in IT systems.

Further elements identified are what could be called the enablers and the characteristics of successful digital supply chains.

Successful digital supply chains are enabled by key environment and techno-organizational antecedents, (such as synergy with suppliers, information intensity) (Ranganathan, Teo & Dhaliwal 2011) together with national cultures (Davis et al. 2014).

Digital supply chain characteristics deserving special attention are Knowledge Management constructs (Raisinghani, Meade 2005), key success factors leveraged (Gunasekaran, Ngai 2004) and larger product ranges (Swierczek, Kisperska-Moron 2016).

So far, consideration was given to the landscape, understanding which supply chain contextual factors should be detected and be shaping also the EU FMD case. However, what is the driving force of this digital transformation? How is value generated within this landscape and through which means?

Information itself is “a driving force of activities along the logistics value” chain (Gunasekaran, Ngai 2004). The need to focus on information is recognized as “little attention has been given to the use of big data analytics for increased information exploitation in a supply chain” (Kache, Seuring 2017) and “research on big data in the domain of business is in preliminary stage” (Mishra, Singh 2016). So there seems to be a significant gap in the current literature when it comes to researching big data analytics’ business advantages in supply chain.

Big data are characterized by four specific dimensions: volume, velocity, variety, and veracity (Richey et al. 2016) and it is expected to create equally opportunities (supply chain visibility, operations efficiency and maintenance) and challenges (lack of IT capabilities/infrastructure and cyber security hindering information sharing) (Kache, Seuring 2017).

Considering the second research question on supply chain benefits, in which areas can we expect these benefits to fall into? What are the new opportunities that a greater availability of data in the supply chain create and are worth to explore further?

Some of the identified benefits of big data in supply chain are a decrease in inventory cost, transport optimization and increased responsiveness. These having a spill over effect across the supply chain (Liu, Yi 2017).

Some early empirical studies on big data in supply chain processes can be found in the literature on smart cities and provide valuable insight on big data application to supply chain. Big data leverages Smart cities infrastructure which otherwise would have no impact on supply chain management (Tachizawa, Alvarez-Gil & Montes-Sancho 2015). In such an environment, new players enter the supply chain, such as city managers, making integration more complex and important (Mehmood et al. 2017). However empirical studies in other supply chain settings seem to be missing, so enriching the literature with studies in different industries would address this current gap.

Research framework and methodology

Through content analysis of the existing literature on digital innovation in SCM, a conceptual framework was developed to understand which contingent variable of the Supply Chain are most relevant during successful digital transformation. This framework will guide the enquiry during the case study. (fig. 1)

Considering that this is a working paper highlighting the preliminary findings of the study, only some parts of the framework will be addressed in this work.

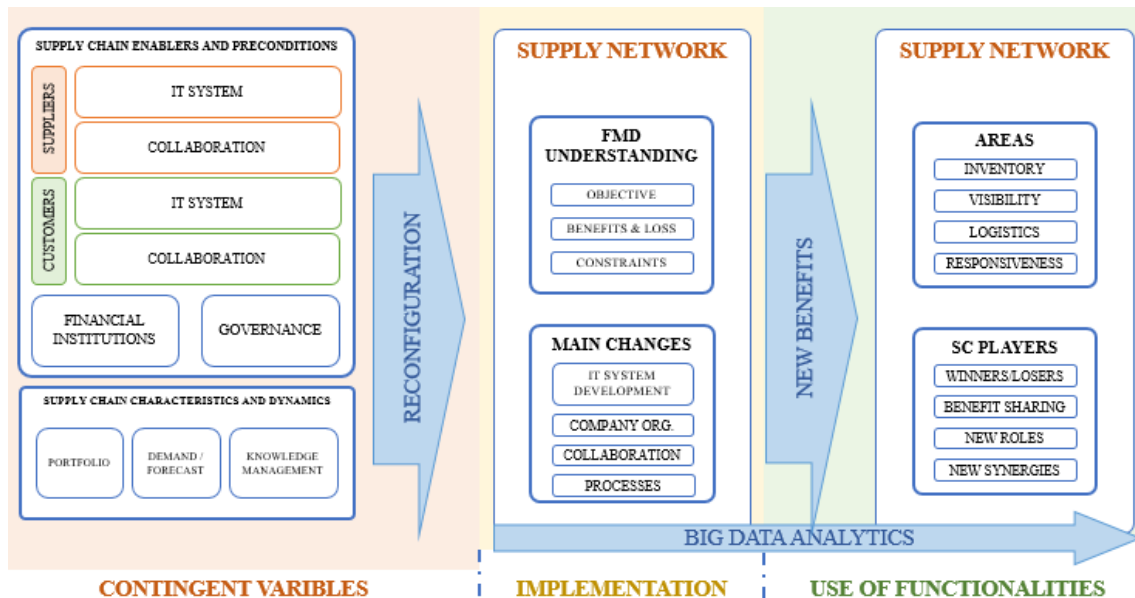


Figure 1 – Research Framework

This framework depicts key SC preconditions and enabler for successful digital transformation such as levels of collaboration, IT maturity (Ranganathan, Teo & Dhaliwal 2011, Lippert, Forman 2006) and supporting governance mechanism to align the different players of the supply chain (Ranganathan, Teo & Dhaliwal 2011, Silvestro,

Lustrato 2014). These, together with some key characteristics of the supply chain such as the knowledge management process used (Raisinghani, Meade 2005), are the contingent variables that lead to a reconfiguration of the supply network, where information itself (i.e. big data analytics) is the driving force of the value chain and leads to the need to redesign processes and collaborative mechanisms (Gunasekaran, Ngai 2004, Richey et al. 2016) and it also requires strong IT developments to leverage its use (Kache, Seuring 2017). This part of the framework supports the first research question by identifying the contingent variables and how they impact the supply chain.

Out of this reconfiguration new benefits are expected to emerge in the areas such as inventory and logistics optimization, responsiveness and supply chain visibility (Kache, Seuring 2017, Liu, Yi 2017), however it is vital to share correctly the benefits across the new SC configuration for these benefits to materialize at all (Richey et al. 2016, Hendrik Haan et al. 2013, Herrmann et al. 2015, Cannella et al. 2015) being conscious that new players could enter the supply chain and new synergies within the chain could develop (Tachizawa, Alvarez-Gil & Montes-Sancho 2015, Mehmood et al. 2017). This part of the framework supports the second research question as it helps to identify the areas where benefits are expected to emerge.

The case study was carried out on the pharmaceutical distribution chain of a smaller northern European country. In such a chain, products are shipped from pharmaceutical manufacturing sites into their contracted national distribution center operating in in the country. Products are then sold to the relevant full line wholesalers who then sell products onwards to pharmacies (1.800 in the country) and sometimes to hospitals (100 in the country). For certain products, distribution centers might sell directly to hospitals or pharmacies.

The study is performed on a single case that covers the whole distribution chain of the country. A single case design was chosen to allow for an in-depth study at a supply network level, across the three tiers in the distribution network.

To select the country for the study, out of the thirty-two countries in scope for EU FMD, different strategies were combined. The country should have been in an advanced stage of EU FMD implementation with key supply chain stakeholders ensuring adequate support in carrying out the study. Finally, a senior expert at EU level recommended countries to involve (reputational selection) based on interest for research and access to data. The researchers have then made the selection out of six eligible countries based on preliminary discussions with leading EU FMD stakeholders from the different countries.

Data collection was performed following a case study protocol developed from the theoretical framework. Data on the key elements of the framework were gathered through documentation (slides, reports) and semi-structured interviews. The relevant documentation was gathered from different sources, publicly available data was searched, company documents were collected during and after the interviews and the researchers had also EU FMD specific documents available as part of one of the researcher's practitioner role in the pharma industry.

Eight semi-structured interviews were run, seven face to face at the interviewee facilities and one via telephone. Interviews have lasted between 30 to 90 minutes each. Two interviews were attended by a team of two people and all the interviews were recorded.

Interviewees represented a significant portion of the supply chain in the country. The two vertically integrated distributor/full line wholesale groups that were interviewed represent 90% of the market turnover and interviews were also done with a pharmaceutical manufacturer and the manufacturers association, two hospitals and a community pharmacy representative, to ensure full coverage of the distribution network.

Furthermore, an interview was also conducted with a company performing a supply chain integrator function in EU FMD.

All interviewees held senior roles in their organization with between 15 to 40 years of professional experience in the sector/industry.

Findings

To develop the preliminary findings of the study, the notes from the interviews were analysed to identify any recurring pattern among interviews and to cross reference information provided by the different interviewees to strengthen study validity.

One of the key themes coming out consistently across the participants was the good level of collaboration developed over a two-year period and the key role played by the formal governance mechanism developed for EU FMD and a new player in the supply chain that we will call the supply chain integrator and describe below.

The EU FMD regulation assigns the accountability to set up and manage the verification system to the supply chain stakeholders (manufacturers/traders, wholesalers, pharmacies and hospitals). The representatives of these stakeholders form a governance group, both at EU and country level, that steers the work of implementation.

These governing bodies also form the board of newly set organizations in the supply chain (at EU level and in every country), tasked with the implementation and running of the verification system. These organizations, called National Medicines Verification Systems (NMVO), act as integrators in the supply chain for EU FMD as they need to bring together and facilitate collaboration across the different SC stakeholders.

In the country being studied, the NMVO has already developed a working system connected with the EU hub and was in the process of starting a pilot in the live system, being among the first countries in Europe doing so.

The role of the governance body for EU FMD and the underlying requirement of regulation compliance have leveraged the collaboration curve among the supply chain participants. All participants have identified the signing of the memorandum of understanding among the governing stakeholders, as a turning point in improving collaboration, while the resulting shared goal has helped in different occasions to move forward the implementation work in a collaborative way. This is also in line with previous findings that an urge for compliance (Co, Barro 2009) and shared goals (Shah et al. 2008) foster a more collaborative approach among stakeholders.

All the participants have also recognised the key role played by the supply chain integrator, in its facilitating function for EU FMD implementation, as a key enabler of collaboration. In such a complex and broad SC project, no single SC player could stand up to adequately coordinate the overall effort, while the supply chain integrator had the mandate, the independence and the international network to steer effective collaboration and reduce conflict among SC players. The need for a credible integrator functions in highly differentiated environments is a key concept of contingency theory (Lawrence, Lorsch 1967).

When it comes to the IT landscape, there is a high variety of IT maturity among the SC players, ranging from global and highly integrated companies, with IT development plans already in place, to publicly owned SC players with limited budget for IT development and highly manual supply chain processes with limited transparency.

The different IT maturity levels seem to derive different kind of benefits for the relevant SC players. The more mature IT players recognize a direct benefit from the additional data generated by EU FMD and are currently thinking on the best way to adapt their knowledge management process to offer new services to customers which are enabled by big data analytics. On the other hand, the SC players with less mature IT

landscapes seem to focus on the BPR needed to comply with EU FMD as a key driver to achieve SC benefits from EU FMD. This is in line with the previous literature about the positive role of mature IT landscapes and trust in technology in achieving benefits from digital supply chains (Ranganathan, Teo & Dhaliwal 2011, Lippert, Forman 2006) and the fact that traceability leads to the development of additional services (Cagliano, De Marco & Rafele 2017). We can then argue that, in order to envisage big data analytics driven benefits in the supply chain, a good level of IT maturity and familiarity with traceability is a needed prerequisite.

Among the possible benefits of EU FMD implementation, all players have mentioned more control over the reverse logistics processes (returns and recalls). This is an interesting finding since the current literature has seldom focused on the positive impact of digital innovation and big data analytics on reverse logistics.

Furthermore, wholesalers and pharmacies have both suggested benefits that would require greater sharing of retail level data, like SC visibility and the possibility to use the data to improve their own operations (inventory optimization and prediction of peaks). However, they also mentioned that a key prerequisite to achieve broader sharing of data rests on further reassurance around minimizing possible cybersecurity threats and an appropriate benefit sharing mechanism. As it was already noted by (Kache, Seuring 2017) and (Herrmann et al. 2015, Cannella et al. 2015).

Finally, hospitals assign high importance to additional investments in automation and the resulting BPR, in order to achieve important benefits such as tracking the flow of medicines within hospitals and thus improving overall business planning.

Discussion

The empirical evidence of this study highlights the role of specific supply chain contingent variables in determining a successful digital innovation process.

The role of governance seems crucial in this study as it is the single most recognized success factor for the implementation of digital innovation. This suggests that in case of very complex changes impacting the vast majority of a supply network, the individual initiatives of pioneering companies, regardless of how powerful and technologically advanced, might not be enough.

Following the original concept of contingency theory, on the emergence of integrative devices to manage highly differentiated contexts needing integration (Lawrence, Lorsch 1967), the presence of a strong and credible supply chain integrator, like in our case, should be regarded as a key factor for successful digitalization in fragmented and heterogeneous supply chains.

Also, the levels of IT maturity and technology trust (Ranganathan, Teo & Dhaliwal 2011, Lippert, Forman 2006) are a key prerequisite to enable the recognition of supply chain benefits driven by the use of big data analytics during a digital innovation process.

As we research the impact of big data analytics in SCM, the influence of these identified contingent variables (governance mechanisms, SC integrators, IT maturity and trust) should be carefully taken into consideration before analysing the expected benefits of digital innovation.

This study also suggests that many of the benefits achievable from a digital innovation process can be reached only after some level of reconfiguration in the supply network. This means both reconfiguring the internal processes of each player (through BPR or the addition of further enabling technology) as well as reconfiguring the processes and relationships among the SC partners in terms of new ways and forums for collaborating and sharing data, since the potential benefits that can accrue to each player are only enabled through trust in technology and mutual sharing.

In this perspective, a supply chain integrator role could facilitate the continuing collaboration journey, supporting the growth of the needed trust and sharing, so to enable the use of big data analytics across the supply chain rather than limited to single players.

Considering the expected benefits, the unanimously recognized benefit was the improvement of the reverse logistics. This suggests a new opportunity to consider in the search for digital innovation benefits. In a context where control over the supply chain is a key requirement, like in pharmaceuticals, having a tighter control over the reverse flow in case of issues is a key benefit of the improved tracing and visibility functionalities.

Conclusion

This paper has described which contingent variables influence the successful implementation of digital innovation in supply chain and what are some of the prerequisites to be able to develop SC benefits from a growing amount of data.

The paper adds to contingency theory in SCM by showing how a supply chain has responded to the changing contextual variables (Sousa, Voss 2008) and has done so through a new case study describing a specific environment (Kembro, Selviaridis & Näslund 2014). The paper supports the need for an integrating function in highly fragmented and complex environments (Lawrence, Lorsch 1967), however it also identifies the role of a strong governing body as a key contextual factor in such cases. Further understanding the role played by governing bodies in SC digital innovation, through the development of additional case studies in different contexts, can be a potential area for future research.

The paper also enquires into the role of IT maturity and technology trust in successful digital innovations (Ranganathan, Teo & Dhaliwal 2011, Lippert, Forman 2006), by showing that without these factors, the benefits that can be derived from an increased use of data (i.e. big data analytics) are not recognizable. A better understanding of which dimensions of technological maturity link to an increased use of data by SC players can be an area for future research.

The strong findings about the benefits expected on the reverse logistics processes suggest more attention, in future research, on reverse logistics as a possible driver of SC benefits from digital innovation.

From a practitioner's perspective, the paper highlights some key points of a roadmap for implementing digital innovation in supply chains. Before the launch of DI initiatives, an uplift in IT system and culture is required, otherwise big data analytics benefits will be out of reach. Time needs to be dedicated to the development of a strong governance across SC stakeholders and to the establishment of an integrator entity, this will save time later, during the implementation process. Finally, process re-engineering needs to become an essential element of the overall change plan, to be able to leverage the potential benefits of digital innovation in full.

This paper has also many limitations. It is, first of all, a working paper, so a fuller analysis needs to be conducted in order to confirm the preliminary findings and potentially uncover new insights. It is also based on a single case on one country, the inclusion of further countries in the study will strengthen findings and offer the opportunity to get additional insights on the differences across contexts.

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