Securing the Post-Covid Pharma Supply Chain: An Empirical Investigation

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Abstract

The pandemic outbreak of Covid-19 has shown the fragilities and vulnerabilities of the Pharma Supply Chain (PSC), leading academics and practitioners to rethink PSCs' flexibility, agility, responsiveness, and resilience. This paper investigates how to secure the Post-Covid PSC by (i) classifying the challenges born of or aggravated by the pandemic; (ii) understanding how solutions enabled by Industry 4.0 technologies can be integrated into a framework to address and solve the above challenges. A theoretical framework was developed from a literature review to achieve these objectives, which was then confirmed and enriched by a multiple case study investigation.

Keywords: Pharma Supply Chain, Case Studies, Physical Blockchain

Introduction

The pandemic outbreak of COVID-19 has shown the fragilities and vulnerabilities of the Global Supply Chain in response to an unpredictable event carrying a massive impact, a so-called "black swan". This unprecedented crisis exasperated already existent issues within Pharma Supply Chains (PSCs). Demand spikes and shortage of essential products (Sharma, Zanotti and Musunur, 2020) were two of the most problematic issues during the first wave of the pandemic and supply shocks within the Healthcare sector (Chtioui *et al.*, 2020). Unavailability of the workforce due to employee absenteeism caused by infections or suspected infections (Cundell *et al.*, 2020), fear of disease (Kumar *et al.*, 2020), or quarantine restrictions (Kovacs and Falagara Sigala, 2021) caused severe disruptions to manufacturing companies.

These issues limited even more the capacity of a struggling supply chain to react to the already chaotic demand, worsened by bullwhip effects (Kovacs and Falagara Sigala, 2021) and “phantom demand” (Okeagu *et al.*, 2020).

However, classifications of all issues and problems affecting PSCs are still scarce within the literature. Therefore, the first research question (RQ) is identified: RQ1 – How can challenges born of or aggravated by the pandemic be classified?

Other than reporting problems and issues, many authors studied several Industry 4.0 technologies as a solution to cope with the challenges born of the pandemic. For example, some authors identified drones as a technological solution to ensure timely and contactless delivery (Chowdhury *et al.*, 2021), while others analyzed the benefits of blockchain and distributed ledger technologies in healthcare supply chains (Jamil *et al.*, 2019).

Despite the solutions proposed in the literature, a comprehensive framework of integrated solutions to cope with PSCs’ is still missing. Therefore, the second RQ is identified: RQ2 – How can solutions enabled by Industry 4.0 be integrated into a framework to address and solve the identified challenges?

To answer RQ1, a Literature Review (LR) has been conducted to collect issues and solutions found by the academic researchers, which will be used to draft the list of challenges.

To answer RQ2, the solutions collected in the LR will be analyzed to extract the common characteristics which will be part of the new theoretical framework. Therefore, the appropriate technologies and paradigms will be selected to be part of the integrated framework. The list of challenges and the theoretical framework will be compared to the results obtained from a Multiple Case Study Investigation of some companies operating in Pharma Supply Chains to validate the obtained results.

Literature Review

Privett and Gonsalvez (2014) identified the “Top Ten Global Health Supply Chain Issues” through interviews and survey data from experts in the sector, who were asked to evaluate the most critical areas within global health and pharmaceutical supply chains. The final results identified ten main issues affecting supply chains, eight of which were confirmed by this LR.

Lack of Coordination (1). Kovacs and Falagara Sigala (2021) underline the importance of coordination mechanisms between different supply chain actors to cope with global disruptions and further state how COVID-19 showed the consequences of lacking international standards.

Inventory Management (2). Bhaskar et al. (2020) state that initial inventories were already low compared to the emergency demand in several countries, and supplies could not be restocked due to export bans, which led to a rise in vulnerability in the procurement of essential equipment.

Absent Demand Information (3). Privett and Gonsalvez (2014) describe demand as being often absent or aggregated, which causes severe issues in procurement and decision-making areas. The current pandemic was characterized by sudden changes in demand, which would have been challenging to cope with in ideal conditions. Still, the chronic absence of clear demand information exacerbated the problem leading to panic buying, thus aggravating shortages (Ayati, Saiyarsarai and Nikfar, 2020) and the bullwhip effect (Kovacs and Falagara Sigala, 2021).

Order Management (5). Okeagu et al. (2020) identified an issue called "phantom demand": customers would order larger quantities than needed, which are lately canceled once their demand is satisfied. This effect creates illusory spikes in demand, disrupting supply chain efficiency, which is forced to re-allocate resources.

Shortage Avoidance (6). Privett and Gonsalvez (2014) mention frequent ordering, frequent replenishment, and emergency orders as common strategies to cope with such a problem. However, such a method could not be employed as usual during the first phase of the pandemic; in fact, export bans and border closures caused a sudden rise in demand which led to stock out of all PPE supplies and, later on, reports of shortages in APIs rose (Bhaskar *et al.*, 2020).

Expiration (7). Okeagu et al. (2020) explain that the best practice is to use a predefined system to monitor stock rotations to avoid product expiry. The consequences of an inexistent tracking system were evident to the United States, which faced long-standing health care supply chain and strategic national stockpile issues that were forgotten after the warnings given during the H1N1 pandemic.

Warehouse Management (8). The interviews conducted by Privett and Gonsalvez (2014) revealed that experts consider warehouse management and storage conditions as significant issues. It includes "poor storage, organization, capacity, and shared space management".

Shipment Visibility (9). On many occasions, authors defined it as extremely difficult to track shipments along the supply chain once it leaves the manufacturer. This is especially true for global supply chains due to their incredible complexity and high-degree ramification; few firms could keep track of lower-tier suppliers, thus reducing visibility and favoring slow responses to unexpected disruptions (Xu *et al.*, 2020).

The abovementioned challenges are also reported in Goodarzian, Hosseini-Nasab, and Fakhrzad (2020) as the "top several global health medicine supply chain challenges", to which *Sustainability* (4) was added. The concept of sustainability is becoming much more critical in medicine supply chain management due to its significant impact on social and environmental aspects, and Sazvar et al. (2021) state that more research on the theme of sustainability in pharmaceutical supply chains should be conducted.

After the LR analysis, *Safety and Trust (10)* was also added to the Pharma Supply Chain Challenges list. Trust is a fundamental aspect of enhancing inter-organizational cooperation; Bhaskar et al. (2020) mention that a "breakdown of trust among supply chain stakeholders" due to middlemen and intermediaries who used opportunistic and unfair business practices taking advantage of the lack of transparency affecting supply chains creates an unhealthy environment in which buyers do not believe data coming from middlemen and suppliers.

Furthermore, it is possible to identify specific routing problems connected to the pharma supply chain and the potential application of unmanned aerial vehicles in logistics. For example, in the *Delivery Recipient* (11) challenge, urban distribution strategies may be configured differently if it is necessary to deliver to a single *quarantined person* or an entire *quarantined area*. There are also two typologies of *Operational Constraints* (12), one related to the *payload* (i.e., Basic, Medicinal, or High-Value Products) and the other one to the *vehicle* used for delivery (i.e., Autonomy, Restricted Flying/Driving Areas, and Possibility of Manual Intervention).

Finally, it is mandatory to consider customers' *Willingness To Pay* (13) for a premium, especially in the case of autonomous and unmanned systems, which are recent and not yet established innovations. From the survey of Pani et al. (2020), it is possible to understand that WTP can be defined as a function dependent on *technological awareness*, *type of goods* (payload), the *criticality of the service required by the user* (service), *risk* *aversion to the possibility of drones having high viral charges* (risk perception), *demographics* (i.e., younger or older population).

The identified Last-Mile Delivery Challenges add to the Pharma Supply Chain Challenges for 13 challenges.

Theoretical Framework

Out of all the technologies and solutions that are part of the I4.0, we have identified two of them with the best characteristics to cope with the identified issues in PSCs: Blockchain and Distributed Ledger Technologies (BDLT) and Autonomous and Unmanned Systems (AUS).

Blockchain and Distributed Ledger Technologies

A Distributed Ledger can be defined as a "decentralized repository of data managed and maintained by many participants, without the necessity of assuming trust among each other" (Di Francesco Maesa and Mori, 2020), and a Blockchain is only one possibility to implement a distributed ledger, which is defined as "a distributed append-only timestamped data structure" (Casino, Dasaklis and Patsakis, 2019), allowing us to have a "distributed peer-to-peer network where non-trusting members can interact with each other without a trusted intermediary, in a verifiable manner" (Christidis and Devetsikiotis, 2016). Both are usually mentioned as Blockchain and Distributed Ledger Technologies (BDLT).

Autonomous and Unmanned Systems

Autonomous and Unmanned Systems (AUS) are among the most exciting and studied technologies in the last years.

AUS are derived from the military sector and can be divided into unmanned aerial vehicles (UAVs), unmanned terrestrial vehicles (UTVs), and unmanned maritime vehicles.

In particular, UAVs have been studied in-depth in the literature, where authors highlighted various advantages in their use for last-mile delivery: a practical step to zero-emission logistics (Pani *et al.*, 2020), provide contactless delivery (Abrar, Islam and Shanto, 2020), independent from transport infrastructures (Choi *et al.*, 2019), offer faster deliveries (Pani *et al.*, 2020), reduce acquisition and operating costs for package delivery (Choi *et al.*, 2019), can provide delivery services in specific scheduled time windows (Choi *et al.*, 2019).

Together, these two technologies are an interesting proposal to tackle the PSCs' challenges. However, they cannot be presented alone. It is necessary to integrate them into a framework that would enhance their benefits. The Physical Internet represents this framework.

Physical Internet

The term "Physical Internet" was first mentioned by Paul Markillie on the front page of The Economist in 2006, where he reviewed all logistics practices at that time. Meanwhile, Professor Benoit Montreuil was enthralled by this term and its possible meaning (Montreuil, 2011), comparing the physical web of logistics services and resources to the Digital Internet. Therefore, from 2009 to 2012, Professor Montreuil gradually released and updated the first version of what is now known as the "Physical Internet Manifesto", where he detailed a new supply chain paradigm based on the concept of "Physical Internet" (Montreuil, 2009).

Professor Montreuil defines the Physical Internet as "an open global logistics system founded on physical, digital and operational interconnectivity through encapsulation, interfaces, and protocols. It is a perpetually evolving system driven by technological, infrastructural and business innovation" (Montreuil, Meller and Ballot, 2013).

Together, these three solutions are the "Physical Blockchain" framework (Fig. 1).

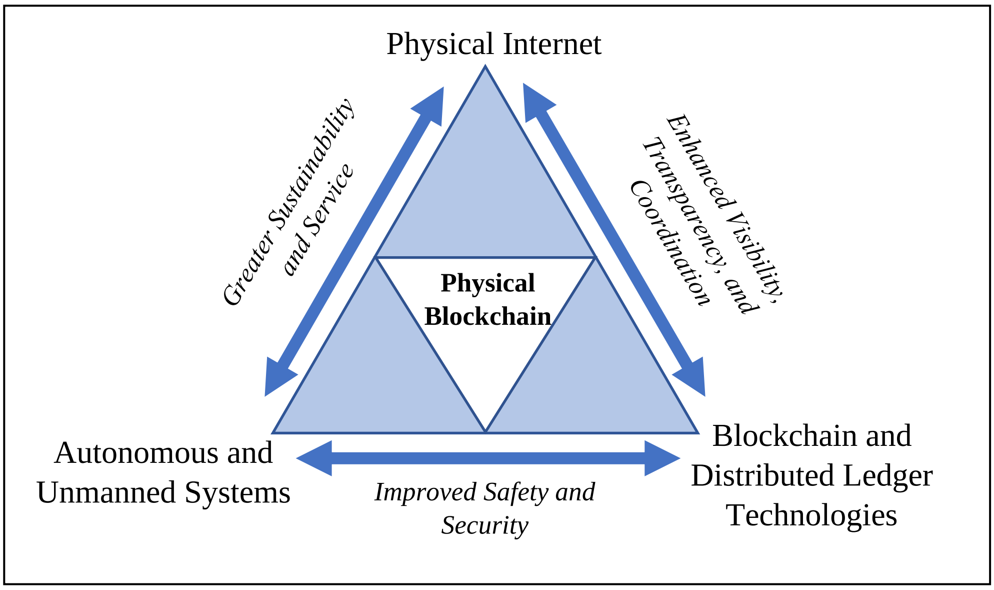

Figure 1. "Physical Blockchain" framework.

Multiple Case Study Investigation

Methodology

This work aims to develop a theoretical framework to solve or scale back the issues identified within PSCs. Therefore, a Multiple Case Study Investigation was adopted as a research method on companies operating in Pharma Supply Chains.

The multiple case study investigation was used to test the validity of the identified challenges in PSCs and compare currently adopted solutions to the theoretical framework developed in this work.

The process of case selection had the aim to include companies operating and covering different roles in the supply chains of the pharmaceutical sector. The following two criteria were included in the selection process:

- *Pharma Supply Chain actors operating at different levels*. For the multiple case study investigation, more pharmaceutical companies and at least one other actor covering other roles within the supply chain were selected.
- *Large companies*. Complex and consolidated supply chains may be more subject to identified issues.

Following the abovementioned criteria, three companies and one consortium were selected as case studies: two pharmaceutical companies, one healthcare consortium comprising several pharmaceutical companies, wholesalers, and intermediate distributors, and one logistics service provider. The low number of identified case studies is justified by Voss, Tsikriktsis, and Frohlich (2002), as the authors underline the opportunity for a more profound observation when considering fewer case studies.

The research instruments were identified to collect data rigorously, and an interview protocol was developed (Voss, Tsikriktsis and Frohlich, 2002). The structured interview was formed by several open questions, which were divided into three parts:

- Description of the company.
- Major problems perceived within the Pharma Supply Chain.
- Major solutions adopted to solve identified issues.

The interviews aimed to understand better the significant issues currently affecting companies operating in PSCs and analyze adopted solutions to curb these problems.

The principal informant was selected (Voss, Tsikriktsis and Frohlich, 2002), such as supply chain managers, logistics managers, and managing directors. All interviews were transcribed and lasted approximately one hour each. The interviewees could correctly answer and explore the open-ended questions first, followed by more specific and detailed questions that came last (Voss, Tsikriktsis and Frohlich, 2002).

Validation of this case research was confirmed following the categories presented by Voss, Tsikriktsis and Frohlich (2002): Construct Validity was ensured through multiple sources of evidence. Internal Validity was guaranteed by building the research on the literature related to issues and solutions of pharma supply chains and the cross-case analysis conducted during the data analysis phase. External Validity was ensured by identifying proper selection criteria and comparing data from companies covering different roles within the supply chain. Reliability was provided by the research protocol developed, which was also validated.

As far as data analysis is concerned, each case was singularly analyzed while categorizing the main issues and solutions reported. Then, a cross-analysis among the four cases was conducted to highlight existing patterns between problems and solutions, and the Physical Blockchain framework.

Interviews and Discussion

The information obtained from the interviews conducted in the multiple case study investigation will be presented below, compared with current knowledge about the literature topics.

Company A (Pharmaceutical Manufacturer) – During the interview, the two main themes brought to light were sustainability and traceability. For the first one, *Company A* felt the need to increase the level of environmental sustainability within their processes, as for the latter, the interviewee underlined the fact that in the past, all information concerned with shipped unit loads (ULs) would be lost during intermediate steps along the supply chain.

Company A recently adopted an innovative solution implemented within the supply chain to solve the identified issues. A new pallet made out of recycled plastic – which is environmentally friendly and more resistant to temperature changes and atmospheric precipitation, safer, easier to sanitize, and ship – is integrated with an RFID tag. Taking advantage of the characteristics of this item, each UL is associated with a pallet – with ad hoc platforms installed within the manufacturer's warehouses to isolate ULs from other RFID tag signals present in the facility – thus enabling enhanced visibility and traceability of the product along the whole supply chain. Currently, *Company A* uses a single RFID tag for each UL; however, the company's representative highlights the possibility of applying an RFID tag on each package to increase further the traceability of the product, which is already being implemented in luxury product sectors – where high-value items justify this choice – and the pharmaceutical industry is close to extending RFID tags usage as well.

The interviewee underlined the success of their innovative solution by stating that several LSPs were interested in adopting these new pallets. However, *Company A* was limited by the current number of existing pallets.

The solution adopted by *Company A* is fascinating as it shares some significant points with π-containers studied in the PI framework: the pallets are made out of recycled plastic and integrated with RFID tags to enable traceability; thus, they could be defined as "smart" and "ecofriendly" as Montreuil, Meller and Ballot (2013) envisioned π-containers.

Company B (Pharmaceutical Manufacturer) – During this interview, the interviewee explored the importance and benefits of adopting innovative solutions for the last-mile delivery. *Company B* is interested in testing UAVs for delivering medicines and drugs to hospitals. The company's representative explained that the most promising market sectors for the employment of unmanned aerial vehicles are the pharmaceutical and luxury items sectors because the high ratio between value and weight of the item per mile justifies the adoption of such a technology.

The interviewee further explained the several advantages of the adoption of UAVs:

- "Elimination" of hospital warehouses and the "wholesaler model". Medicines and drugs would be quickly delivered when needed because hospitals do not need item stocks but beds to recover patients.
- Avoiding high traffic areas. It can increase the delivery speed while reducing traffic and CO_2 emissions simultaneously.
- Presence of strategic centers within the city. It would decrease the response time in case of emergencies.
- Saving lives. A drone would be able to deliver life-saving drugs in a shorter time, thus potentially saving more lives.
- A more sustainable, quicker, and cheaper solution.

Furthermore, the box containing medicines carried by the drone would be equipped with a sensor to monitor the temperature.

The company analyzed and prepared the project on paper, discussing with ENAC to ask for the necessary permits and requirements to test and validate the project.

The advantages of UAVs identified by the interviewee align with the literature.

Healthcare Consortium – The consortium's representative agreed that *blockchains* enabled trustless structures and smart contracts will be a valuable tool in the future; however, currently, most companies fear antitrust entities' sanctions if essential data are shared within the supply chain. Nowadays, pharmaceutical companies perceive as critical information to share with their suppliers stock quantities in their inventories – thus creating an unfair competition, which would lead *antitrust* entities to take action.

This is not surprising; in fact, EU Antitrust laws are stringent concerning unfair competition. A Q&A recently released by Baker Botts – an American multinational law firm – clearly explains to their clients EU antitrust risks when exchanging information. Prices and quantities are reported as high-risk information in the document. Companies may also incur liability simply receiving unsolicited information in a one-time exchange or in the case of public exchange (Hatton, Vasbeck and Comtois, 2020). Even the exchange of information between non-competitors could raise concerns in case of indirect exchanges; therefore – to mitigate risks – Baker Botts suggests to "avoid any exchange of forward-looking data on sensitive issues such as prices and quantities".

However, several actors part of the *Healthcare Consortium* started to employ the electronic shipment document, which helped speed up inbound operations.

Another interesting issue that the interviewee raised is the challenge presented by horizontal collaboration: several LSPs may collaborate on night-time shipments – thus maximizing transported volume, reducing fuel consumption and CO_2 emissions, and leading to a more efficient and effective service -; however, this could never happen for day-time shipments due to "visibility issues" – i.e., the customer would not see that all LSPs are delivering the service – even if they are aware of the benefits of collaboration.

The literature confirms this issue as well. Horizontal collaboration is one of the main themes of PI – i.e., without cooperation, it is not possible to create an open logistics web – and it is the research topic of (Simmer *et al.*, 2017), where the authors interviewed several logistics companies in Austria. In this article, the interviewees stated that "cooperation with competitors is inconceivable" in fact, several partnerships are started only to extend geographical coverage. Therefore, the identified vital drivers were "serving larger customers, requirements of customers and benefits for both companies", while the negative experiences which impacted cooperation were "missing corporate culture, envy, lack of confidence, antitrust fines" – confirmed by the *Healthcare Consortium*'s representative – "and the high administrative input".

Company C (Logistics Service Provider) – In this interview, the issues of visibility and antitrust laws were raised again. Concerning the first one, the interviewee explained the adopted solutions to enhance their service: sharing with their customers' clients how many and which products are present in a UL and monitoring high-value products (so-called "strengthened logistics") – i.e., scanning all ULs bar codes and sharing these data with AIFA, to know what products are going to which companies.

On the other hand, when mentioning antitrust laws, the interviewee answered that only data concerning logistics operations are being shared – which are not considered sensitive information – and customers' clients already have these data in the electronic shipping document – developed by *Healthcare Consortium*. Therefore, *Company C* only speeds up inbound operations by sharing these data.

Furthermore, *Company C* implemented *Company A*'s solution, which is described as a unique model with some critical issues: *Company A* has total control over its supply chain – which is not a common occurrence –, it is expensive, and it requires to change current processes, and it would be necessary to have all customers and actors to adopt it. Otherwise, there would be the risk of increasing logistics inefficiency since LSPs would have to split their processes to follow different models.

Conclusions

(RQ1) Through a LR, ten supply chain issues and three last-mile delivery problems have been identified, representing the 13 Pharma Supply Chain Challenges.

(RQ2) During the LR, the solutions proposed by the authors were collected, which were analyzed to find the common characteristics that the framework should possess. The result was the selection of three new technologies and paradigms, which were included in the new "Physical Blockchain" framework: Physical Internet, Blockchain and Distributed Ledger Technologies, and Autonomous and Unmanned Systems.

Finally, to further validate the challenges obtained from the LR and the newly developed Physical Blockchain framework, a multiple case study investigation was performed on four companies that operate in a Pharma Supply Chain. On the one hand, the interviews with the representatives of these companies highlighted issues regarding shipment visibility, environmental sustainability, antitrust laws, horizontal collaboration, and last-mile delivery. Thus, validating some of the challenges identified in the LR. However, antitrust laws will need further study before being included with the other challenges, as they did not come out in the LR.

On the other hand, the solutions adopted by these companies were inclined towards the themes of sustainability and digitization, employing solutions similar to those included in the Physical Blockchain. For example, the pallet made of recyclable plastic with an integrated RFID tag (mentioned by Company A) is very similar in concept to the π-containers of the Physical Internet, which have a great potential to enhance shipments traceability – through the use of RFID tags – and to facilitate storing and handling operations as well. Furthermore, with the implementation of blockchain and distributed ledger technologies, it will be possible to work in trustless and safe environments by sharing necessary data and automating processes through smart contracts.

The Physical Internet provides other benefits to cope with the challenges. PI-inventory models generally perform better than traditional solutions, especially during disruptive events – thanks to the possibility to share resources – and decrease the logistics cost, allowing inventory flows to quickly adapt to changes, thus improving the overall flexibility of the supply chain.

Company B brought UAVs as a possible solution for the last-mile delivery of drugs to hospitals, confirming the potential of this I4.0 technology in our framework. UAVs are independent of existing infrastructures; therefore, they can easily reach any location (e.g., inaccessible areas to traditional means of transport, quarantined sites which cannot be entered by human personnel) faster than current transports and reduce last-mile delivery logistics costs.

Overall, the Physical Blockchain framework presents several benefits and a potential solution to cope with the identified challenges. However, it will be necessary to study further how these technologies would interact with each other within the Physical Internet paradigm and what would be the steps required for companies to move from the current situation to reach the state described in the Physical Blockchain ultimately.

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(The complete list of references and the interview protocol for the multiple case study investigation are available under request.)

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