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DISRUPTIONS, RECOVERY STRATEGIES AND THE PHARMACEUTICAL SUPPLY CHAIN; EMPIRICAL EVIDENCE FROM FIRST TIER CUSTOMERS IN THE UNITED KINGDOM

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Abstract

Purpose: The aim of this research therefore is to explore the causes of drug shortages within the pharmaceutical supply chain and assess the adopted mitigation strategies.

Research Approach: The study is carried out from an inductive perspective where we seek to understand the phenomenon by a detailed review of extant literature followed by a series of semi-structured interviews with first tier consumers within a case study framework. The respondents were chosen using purposive sampling as those best to comment on the phenomenon under scrutiny. Data was analysed using thematic analysis, where a dual focus was adopted; 1) the preliminary focus was on the identification of system themes (where the system was impacted and the responds e.g. complexity, disruptions and product alternatives) and 2) the secondary focus was the impact on the patient as system recipient and product user (where themes such as stress, anxiety, and adverse drug reactions emerged).

Findings and Originality: The analysis show that drug shortages within the pharmaceutical supply chain in the UK occur as a result of stringent regulatory frameworks, faults in the manufacturing processes, lack of Active Pharmaceutical Ingredients, monopolistic wholesaler markets; lack of information dissemination, offshore trading and price manipulations for profit. The impact on the consumers is reported to be extensive and can endure long after the disruptive event occurs. The findings indicate that existing recovery strategies are however cumbersome, add complexity to the supply chain and in extreme cases facilitate the infiltration of counterfeits. The study is innovative as it explores disruptive events and associated recovery strategies which have not been adequately addressed in supply chain management studies to date.

Research Impact: This research contributes to existing literature by extending discussions on supply chain disruptions within a dynamic supply chain whilst focusing on product service supply chain recovery strategies and mechanisms.

Practical Impact: This study provides Operations/Supply Chain Managers and Pharmaceutical companies and professionals with strategies that can be adopted can adopt in reducing and recovering in a more resilient manner to disruptive events. This thus presents the bedrock for resilient practice and systems design and development, thus reducing system vulnerability and ultimately leading to improved product availability and patient care.

Introduction

This study examines the causes of drug shortages as a disruptive event in the UK pharmaceutical supply chain. More specifically, the study seeks to explore why the pharmaceutical supply chain are susceptible to drug shortages. This is pertinent because, drug shortages are defined as a supply issue that affects

how the pharmacy prepares or dispenses a drug product or influences patients care (Panels, 2015), and has become a global phenomenon which has risen significantly over the last decade (Pauwels et al., 2015). For instance, a survey on drug shortages by European Association of Hospital Pharmacists (2015) revealed that 99% of pharmacists in European hospitals experienced drug shortages in the year under review. Drug shortages is potentially detrimental to the patient as well as members of the supply chains as it can harm treatments, delay medical procedures, and result in medication errors (De Weerd et al., 2017). This study therefore seeks to contribute to existing supply chain literature by examining the weaknesses that make the supply chain susceptible to drug shortages. This section provides the background to the study; the next section explores concepts related to understanding drug shortages within the supply chain literature, while section three will present the methodological approach. The study concludes in section five with a conclusion and recommendation for best practice.

Literature Review

Supply chain disruptions which are events that disrupt the normal flow of goods and services within a supply chain have been reported to have adverse effects on the financial and operational performance of the firm (Schmidt and Raman, 2012; Urcioli et al., 2014; Thekdi and Sarvos, 2016). This notwithstanding, the research on this topic has received limited empirical attention (Bode et al. 2011; Simangunsong et al., 2012). It is also purported that existing literature tends to examine disruptive events as homogenous, in spite of the fact that they have varying causes and effects as well different mitigation strategies (DuHadway et al., 2017). Supply chain disruptions can therefore be classified based on the sources of disruptions which could be exogenous or endogenous (Hendricks et al., 2009; Urcioli et al., 2014; Gunasekaran et al. 2015); action of the disruption as intentional or unintentional (Marley et al., 2014); as well as impact of the disruption as dynamic or stable (Saghafian and Van Oyen, 2016).

Similarly, supply chain complexity (Wagner and Bode, 2016), supply chain structure (Craghead et al., 2007), the characteristics of the supply chain (Wagner and Bode, 2009), global sourcing as well as outsourcing (Christopher and Holweg 2011) have been suggested as elements that increase supply chains vulnerabilities to various disturbances (Craighead et al., 2007; Ellis et al., 2011; Chopra and Sodhi 2014) and economic factors such as wage inflation in lower cost countries (Wagner and Neshat 2012). For instance, the Japanese earthquake and Tsunami in 2011, which disrupted the supply of glycine (an ingredient for solid-dosage products and the gelatine used in soft gel capsules -(Miller 2011))- in some pharmaceutical supply chains exposed these supply chains to various risk as a result of the complex multi-layered supply chain as well as outsourcing.

However, empirical evidence exploring vulnerabilities of the pharmaceutical supply chain is limited. For instance, Breen (2008) explored the nature and prevalence of risk in the pharmaceutical supply chain and identified 35 risks the supply chain was exposed to. Also, Quadri et al., (2015) explored the causes of antibacterial shortages from 2001 and 2013 in the US, using the Utah database of drug information, they found that a total of 148 drugs were short in supply over a 13 year period. This study however fails to explore why these drug shortages occurred and how they were being tackled. Similarly, Pauwels et al.,(2015), studied the characteristics, effect, causes and management of drug shortages of hospital pharmacies in Europe and find that drug shortages were caused parallel trading, tendering and manufacturing problems. This study however examined only hospital pharmacists and explored it from a clinical perspective. In view of this, there is need to examine in detail why the pharmaceutical supply chains are susceptible to drug shortage, from an operations management perspective. As such, this study hopes to answer the following questions: Why is the pharmaceutical supply chain exposed to dynamic disruptions like drug shortages? How do pharmaceutical supply chains mitigate the impact of these disruptions?

Research Strategy and Design

The case study approach which is a rigorous and well established research method was chosen as the research strategy (Yin, 2013). The case study was considered appropriate as it presents an avenue for the researcher to investigate a phenomenon in a real life setting as well as suitable for research areas with limited pre-existing theories (Gibbert, et al., 2008).

Data for this study was gathered in two separate stages, where multiple data sources and different data collection methods was employed. The first stage began with a review of literature using the systematic literature review approach, to understand the underlying constructs of supply chain disruption as well as to effectively classify the phenomenon under study. The next stage involved the selection of the case study. The convenience sampling technique was the criteria for selecting the case study. An invitation to participate in the research was circulated and interviewees who positively replied to the invitation were used. Multiple case studies were employed which provided depth as well as breadth to the study (Yin, 2013). The first tier consumers which are pharmacists, were specifically selected for this study , as the study draws upon the definition of drug shortages by Panel(2009)-*A supply issue that affects how a pharmacy prepares or dispenses a drug or influences patients care-*.' This suggests that the bane of drug shortages rests on pharmacist within the pharmaceutical supply chain.

Prior to the interview, the participants were sent an interview protocol and a leaflet which provided a brief of the research. In line with case study guidelines highlighted by Yin (2013), the first two interviews were conducted on the participants' premises where each interview lasted between 30-45 mins. However whilst analysing these interviews, the need to explore other categories of first tier consumers arose, as such the snowballing technique was employed to access hospital and online pharmacists. As such: the total numbers of participants were two community pharmacists, 1 online pharmacist and two hospital pharmacists. The participants however choose to remain anonymous with regards to the study. The interviews were audio-recorded after receiving consent from the interviewee and then transcribed manually following the 24 hours recommendation as highlighted by (Blackhurst et al., 2011). The transcripts were coded and analysed using a software package called Nvivo.

Analysis of Data

In order to deliver to the study aim, during the interview, participants were asked the following: what is your understanding of drug shortages and why do you think drug shortages occur. The findings are described in accordance with existing literature and matched with excerpts from the transcripts. Table 2 below presents a summary of the analysis of the study.

Table 2 Causes of Drug Shortages

Emerging themes	Definition In Literature	Excerpts from Interviews
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Manufacturing Processes	The manufacturing process of a pharmaceutical which is tagged as cumbersome is another highlighted factor that exposes the supply chain to drug shortages. These manufacturing processes may range from the failure of the product to reach the desired quality as stipulated by the regulating bodies, or the lack of raw materials which most times is sourced outside the manufacturing regions.	<p>Hospital Pharm. 1 ‘A product recall can cause a drug shortage and this can happen for instance if the firm discovers that a batch of drugs that had gone out, did not meet the quality requirements’.</p> <p>Hospital Pharm. 2 ‘The MHRA regulates the quality of drugs produced for consumption in the United Kingdom for the right grade and the right ingredients, if a firm fails the quality check in the production of raw materials, they will have to reorder it, sometime these raw materials come from different parts of the world which may take weeks to get. These create a backlog in the production processes and hence cause drug shortages’.</p> <p>Community Pharm. 1 ‘A break down in the manufacturing plant or something as trivial as a change in packaging can upset the whole system. Like with the Glucopen recall where they could not source for the active ingredients’.</p>
Managerial Practices	The managerial practices of the firm also weaken the system which in turn makes it impossible for the system to resist drug shortages when they occur making it vulnerable to various risks (Blackhurst et al, 2011). This is evidenced from the data, For instance, an informant explained that some manufacturers had to adopt the managerial practice of rationing drugs supplied to wholesalers and pharmacists, to curb wholesalers and some pharmacists who sold medicines abroad because they were more profitable. While this strategy was effective for a while, it however leads to drug shortages in the long run (Bogaert et al., 2015).	<p>Community Pharm.2 ‘We also have incidences of manufacturing firms rationing drugs we buy and supply the drugs based on a quota system. For instance last month we had to fight a manufacturer because our quota for a particular drug was zero and we had two patients on this drug which will cause a shortage. I think manufacturing firms decided to start selling drugs on quota system to curb the incidence of wholesalers or even some community pharmacists who were selling drugs abroad for profit’.</p> <p>Hospital Pharm.1 ‘Manipulation of the market for profit, like what happened with pain killers-Codeine- a few years back, firms withheld products to create artificial scarcity, because they had forecasted a level of sales which had not been attained, they created artificial scarcity, increased the prices by about a couple of pennies and then re-introduced it back into the market when the agitation was high. Sometimes, artificial scarcity maybe because of the NHS price lists which makes profit margin quite narrows.’</p> <p>Community Pharm.1 ‘Selling of drugs abroad for profit is one major cause of drug shortages. Some wholesalers and even community pharmacists who have licences to trade, will buy drugs at a cheaper rate from the manufacturers and sell overseas especially within the EU region for profit creating drug scarcity. Sometimes, these wholesalers will have to repurchase these drugs again from overseas as a result of the quota system introduced by the manufacturing firms’.</p> <p>Online Pharm. 1 ‘A whisper that a drug is going out of circulation may cause panic among pharmacists. Then we order about three months’ worth of the drugs, to save for the rainy day. This will cause the drug to become scarce in the market and then the prices will go up. Sometimes we get to sell to other community pharmacists for a gain’.</p>
Supply Chain Characteristics	Supply chain characteristic which depicts buyer supplier relationship includes; supplier dependence and consumer dependence. Supplier dependence is the degree to which a firm sources its inputs from a single supplier to alternative suppliers (Wagner and Neshat,2012; Peck, 2005).	<p>Community Pharm. 2 ‘Let’s say there is only one supplier that supplies a drug, and the supplier fails a quality check of raw materials, they may not be able to meet up production capacity which will cause the drug to become scarce. This happened with the case of Lazoprizole several years back’.</p> <p>Community Pharm.1 ‘Usually manufacturing firms use historical records of patients and the consumption pattern of a particular drug to determine the quantity it will produce. Sometimes they do not forecast correctly, as the number of consumers may vary depending of change in lifestyle. Take for instance anti-depressant drugs’.</p>

Supplier Selection	Supplier selection refers to the process of selecting a supplier based on price negotiation and the ability to share in supply and demand risk (Chopra and Meindl, 2007).	Hospital Pharm. 1 <i>'Sometimes it may not necessarily be a drug shortage as it may be the hospital management board's decision not to stock it on its formulary. For instance, I had a patient who came in yesterday and is taking lycionpril and hydrochrothyzine combination, we did not have it at the hospital, it was a local level decision not to stock the product.'</i>
Supply Chain Design /Structure	The structure of the supply chain deals with the design of the chain, which can either be centralized or decentralized (Yang et al.,2015)	Online Pharm. 1 <i>'I think the way the supply chain in the pharmaceutical industry is designed makes it difficult to access drugs. I feel smaller firms are penny pinching as they really do not make any profits. What really is is that we have the manufacturers and three major wholesalers who own and control the biggest retail stores/community pharmacies. Although there are short liners (small wholesalers), they sell basically generic drugs. When a drug is in short supply at the retail level, the big retailers simply meet their wholesalers or the multiple company for while small retailers have to get the drugs at a more expensive rate.'</i>
Lack of Information sharing	Information sharing is necessary for integrating a supply chain (SC). To achieve efficiency, members in a supply chain are expected to collaborate in managing material, information and financial flow(Bian et al., 2016;Riley et al.,2016)	Community Pharm. 1 <i>'In most cases, the manufacturing firms do not give reasons why we can't have a drug. You may call them to find out but you really can't get any information from them. Sometimes this information is required so we can explain to the patient better on why their drugs are unavailable. Also the firm should forewarn us in advance so we can be proactive because whispers may just lead to more shortages.'</i> Community Pharm. 2 <i>'Your relationship in the market place is vital as lack of relationship will limit your information, increase the amount of shortages as well as lead to huge losses.'</i>

4.2 Response of Drug Shortages to the Pharmaceutical Supply Chain

The study also asked how the firms managed drug shortages. The responses show that drug shortages have adverse effect on the supply chain as well on the patients. For instance, the study shows that trust between members of the supply chain are eroded when drug shortages occur. Sometimes this severance in trust may be between the patient and the pharmacists, the pharmacists and the wholesaler or even the manufacturer.

Table 3 Impact of Drug Shortages on the Pharmaceutical Supply Chain

Impact within the PSC	Excerpts from Transcript
Eroded Trust This is consistent with extant studies arguing that, under high trust conditions, the proclivity of economic actors to be opportunistic decreases, whereas under low trust conditions economic actors are more likely to behave opportunistically.	Community Pharm.1 <i>'Sometimes when we receive a whisper that a drug is going out of circulation may cause panic among pharmacists. Then we order about three months' worth of the drugs, to save for the rainy day. This will cause the drug to become scarce in the market and then the prices will go up. Sometimes we get to sell to other community pharmacists for a gain'. 'If we decide to offer alternatives to the patients, some of them react psychologically'. I had a patient who had tried every form of anti-depressant and she reacted to them in various ways. Then she came to the pharmacy one day to pick up her drugs-the only combination that worked for her and I had to inform her that her drugs were unavailable. She actually went into a fit; I spent the best part of that day trying to reassure her that her drugs will be with her soon. Calling</i>

Exposure to Risk (Financial, Security, Counterfeiting)	<i>the GP to re prescribe an alternative was also a hassle'</i> Community Pharm. 1 <i>'When a patient comes to collect his prescription and its unavailable, after we have tried our possible best to get more stock and we can't seem to be making a headway, we ask the patient to go out and look for the drug'</i> Community Pharm. 2 <i>'Although we have never seen a counterfeit in our pharmacy, I have had a patient who went overseas on holiday and could not travel with his regularly drug. When he got back he had purchased a drug and asked me to confirm its authenticity'</i>
Supply Chain Complexity	Community Pharm. 2 <i>'Delay in patient's treatment occurs when we the pharmacist will have to call the receptionist to inform the GP that the prescribed medicines are unavailable. The GP has to go through the patient's medical history to understand the medical situation, before re prescribing an alternative. This process may take a couple of hours or even days and we as community pharmacists have no power to prescribe alternatives'.</i>

Another effect of drug shortages is that the patients are also exposed to safety risks and financial risk as the patient may seek for alternative drugs outside the supply chain. Also, by seeking alternatives outside the supply chain, patients may knowingly or unknowingly purchase counterfeits. Consistent use of the alternative drug may also affect forecast of the alternatives and lead to the shortage of the alternative drug as well. Drug shortages can also delay patient's treatments as the source for appropriate alternatives continues which can lead to adverse drug reaction and complications. Sometimes, patients may react to drug shortages psychologically which may lead to several complications. The pharmacists are also stressed from having to explain to the patients the need for an alternative as well as seeking for the alternative. The need to call the GP to re-prescribe further complicates the supply chain and lengthens patients' delivery processes.

The findings also reported that mitigation strategies employed by pharmacists were the use of alternatives and sometimes stock piling if notification of a shortage was provided in a timely fashion. The use of alternative however is cumbersome as there is the need to understand the patients profile in order to come up with suitable alternative. The respondents felt that at times the medicines 'matching' process can fail, leading to a failure in the system. This implies that when a whisper is acted upon and it is not necessarily true, firms may not trust the information and resent the operational rework that they have had to undertake. Similarly, if firms get to know the reason for the drug shortage, like unethical hoarding of a product or parallel trading, trust is destroyed.

Conclusion

The aim of this research was to examine why drug shortages occurred within the pharmaceutical supply chain as well as assess the adopted mitigation strategies. The study was carried out from an inductive perspective where semi-structured interviews with first tier consumers within a case study framework was carried and analysed using thematic analysis. The findings show that the pharmaceutical supply chain in the UK is vulnerable to drug shortages as a result of managerial practices, manufacturing processes, supply chain characteristics, supplier selection and lack of information sharing. The study also

finds that these vulnerabilities expose the supply chain to financial, operational and safety risks. Similarly, the supply chain becomes more complex as a result of the adopted mitigation strategies and in some cases creates drug shortages in alternative supply chains.

Further areas for research should seek to understand these mitigation strategies and identify resilient strategies that will minimize the supply chains systems response negatively.

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