



Supply chain risk management strategies in normal and abnormal times: Policymakers' role in reducing generic medicine shortages

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ABSTRACT

Purpose

This paper links supply chain risk management to medicine supply chains to explore the role of policymakers in employing supply chain risk management strategies (SCRMS) to reduce generic medicine shortages.

Design/methodology/approach

Using secondary data supplemented with primary data, we map and compare seven countries' SCRMS for handling shortage risks in their paracetamol supply chains before and during the first two waves of the COVID-19 pandemic.

Findings

Consistent with recent research, the study finds that policymakers had implemented few SCRMS specifically for responding to disruptions caused by COVID-19. However, shortages were largely avoided since multiple strategies for coping with business-as-usual disruptions had been implemented prior to the pandemic. We did find that SCRMS implemented during COVID-19 were not always aligned with those implemented pre-pandemic. We also found that policymakers played both direct and indirect roles.

Research limitations/implications

Combining longitudinal secondary data with interviews sheds light on how, regardless of the level of preparedness during normal times, SCRMS can be leveraged to avert shortages in abnormal times. However, the problem is highly complex, which warrants further research.

Practical implications

Supply chain professionals and policymakers in the healthcare sector can use the findings when developing preparedness and response plans.

Social implications

The insights developed can help policymakers improve the availability of high-volume generic medicines in (ab)normal times.

Original/value

We contribute to prior SCRM research in two ways. First, we operationalize SCRMS in the medicine supply chain context in (ab)normal times, thereby opening avenues for future research on SCRM in this context. Second, we develop insights on the role policymakers play and how they directly implement and indirectly influence the adoption of SCRMS. Based on our findings, we develop a framework that captures the diverse roles of policymakers in SCRM.

Keywords: Medicine supply chain, Medicine shortages, Supply Chain Risk Management, COVID-19, Paracetamol, Policymakers.

1. INTRODUCTION

The COVID-19 pandemic led to initial medicine supply shocks worldwide, exposing the vulnerability of medicine supply chains at full scale (Ayati *et al.*, 2020; McGarry *et al.* 2020; Romano *et al.*, 2021; Sodhi *et al.* 2021). Medicine shortages were already an increasing global problem in normal times before the pandemic (Beck *et al.* 2019; EAHP, 2019; FDA, 2019). In particular, there has been a large-scale increase in off-patent (that is, generic) medicine shortages in recent years (Scholz 2020; DiPiro *et al.* 2021). While policymakers in numerous countries had discussed strategies to address such shortages, few had implemented them by the time the pandemic struck (de Vries *et al.*, 2021). This suggests that countries were at least aware of challenges an abnormal situation such as a pandemic could pose and were able to use this knowledge to respond rapidly to address resultant medicine supply issues caused by COVID-19. Self-reporting by various countries suggests that they successfully avoided shortages. What they did and how this compares with established supply chain risk management strategies (SCRMS) in the extant literature are the empirical issues that motivated the present study.

The pandemic has increased the attention given to supply chain risk management (SCRM) in both academia and practice (Sodhi and Tang, 2021). Broadly defined as efforts to identify, assess, mitigate, and respond to risks, SCRM refers to “supply chain solutions that ensure supply continues to meet the demand in case of a disruption or soon after the occurrence of such a disruption” (Sodhi and Tang, 2012, p. 304). SCRMS were originally developed for commercial enterprises with a focus on potential strategies that *companies* (can) adopt in preparedness for potential disruptions (Ho *et al.*, 2015). The pandemic has led to increased governmental interest in the vulnerability of supply and the level of preparedness for critical product supply chains such as medicines (EU, 2020; EU, 2021). Simultaneously, there have been increasing calls to explore the role of *policymakers* in SCRM (e.g., Darby *et al.*, 2021; Ho *et al.* 2015; Jered *et al.* 2013; Pournader *et al.* 2020). The present paper responds to these calls and aims to develop an understanding of the role of public decisionmakers – hereafter referred to as policymakers – in dealing with medicine shortages.

Furthermore, it is only very recently that the operations and supply chain management (OSCM) community has started to earnestly explore the drivers of and solutions to shortages in medicine supply chains (De Vries *et al.* 2021), particularly from a SCRM perspective (Hopp *et al.* 2022; Yaroson *et al.* 2021). Accordingly, we focus on the relevance of well-established SCRMS for policymakers. Finally, given the involvement of policymakers in efforts to avert medicine shortages during the first wave of the COVID-19 pandemic, we aim to understand this in the context of (ab)normal times, thus studying differences and similarities before vs. during COVID-19. Understanding how countries who might not have been prepared in terms of SCRMS, but still managed to cope with this large crisis by employing SCRMS after the fact, is an important step in developing knowledge on how (much) to invest in preparedness versus what SCRMS can be implemented when the crisis has occurred. In doing so, we aim to establish how policymakers can employ SCRMS both in preparing for and responding to disruptions. Policymakers can implement measures themselves, such as establishing emergency stocks of essential medicines. They can also incentivize others, such as wholesalers or manufacturers, to do so. We pose the following research questions: *Which SCRMS were in place before COVID-*

19 to reduce generic medicine shortage and which came in place during the pandemic? What role did policymakers play in employing or adopting SCRMS?

This study is part of a large research project on shortages of generic medicines and focuses on off-patent generics. Although they are most often in shortage (Bogaert *et al.* 2015; WHO 2016; FDA, 2019), there is a paucity of risk management research within this context (c.f., Ergun *et al.* 2022; Hopp *et al.* 2022; De Vries *et al.* 2021; Senna *et al.* 2021). In the present study, we adopt a case study approach and focus on the paracetamol supply chain because it exemplifies a commonly used essential generic medicine (WHO, 2021). In addition to being susceptible to shortages (Olivier, 2021), it was among the most highly used medicines in the initial phase of COVID-19 (Research and Markets, 2021; Chrysoloras, 2020; The Telegraph, 2022; EU, 2021). To achieve generalizability of insights, we compared seven countries' SCRMS before COVID-19 with those during the first two waves to understand if and how SCRMS changed during the pandemic. We employed an abductive approach (Kovacs and Spens, 2007) to systematically analyze secondary data from reputable public sources and primary interview data.

We contribute to prior SCRMS research in two ways. First, we respond to calls for more empirical research (DeVries *et al.* 2021) by operationalizing SCRMS in the medicine supply chain context in (ab)normal times, thereby opening avenues for future research on SCRMS in this context. Second, we answer the calls for research taking policymakers' perspectives (Duijzer *et al.*, 2018; Yarosan *et al.* 2021) by developing insights on the role that policymakers play in mitigating medicine shortage risks, and particularly how they directly implement and indirectly influence the adoption of SCRMS. Based on our findings, we develop a framework that captures the diverse roles of policymakers in SCRMS. Our study may also be relevant for other sectors and the role policymakers can take in improving supply chains to reduce risks in both abnormal and normal times. The rest of this paper is organized as follows. Section 2 reviews the literature. The research design is described in Section 3, before Sections 4 and 5 present and discuss the results respectively. Section 6 draws conclusions and suggest future research opportunities.

2. THEORETICAL BACKGROUND AND RESEARCH FRAMEWORK

2.1 Generic Medicine Supply Chains

Medicines that are no longer protected by patents or other exclusivity rights are called "generic" medicines, which means that any company may produce a medicine with the same active pharmaceutical ingredient(s) (APIs), as long as it meets national regulatory requirements. The vast majority of medicines used in most countries are generic. In the UK, for example, generic medicines constitute 81 percent of all prescribed medicines in primary care (Hannay, 2022).

Policymakers may intervene through regulations or incentives to ensure a stable supply of high-quality medicines. However, these interventions aim to seek positive outcomes in a highly complicated landscape. Manufacturing processes are technically complex, and components come from geographically dispersed companies. Due to confidentiality of supplier information, policymakers have a limited understanding of supply chain geographical dependencies, manufacturing lead-times, and supply chain resiliency, all of which differ per medicine (see for example Årdal *et al.* 2021). Furthermore, the industry is highly regulated to ensure medicine safety. Policymakers use tools such as prepositioning, imposing penalties for supply failure, and applying pricing pressure to achieve the highest possible cost savings. For example, when a medicine becomes generic, Norway automatically cuts the reimbursement rate by over 80 percent within two years (NIPH, 2022). Hospital tenders are often solely determined by the unit price, provided that all competitors meet the quality and regulatory standards (WHO, 2019).

Two gaps identified in extant research are particularly relevant to our study. First, research in OSCM has hardly been concerned with medicine shortages (de Lima *et al.* 2018; Tucker *et al.*, 2020). A systematic literature review by De Vries *et al.* (2021) concluded that there is very limited empirical evidence on SCRMS for medicines. Our updated review (see online supplementary material) confirms that this has not changed. Second, there have been calls for research providing evidence-based analyses that can support policymakers in their decision-making (Duijzer *et al.* 2018; EU, 2021; Yaroson *et al.* 2021). We seek to address these gaps by focusing on the role of policymakers in SCRMS and use generic medicine shortages as the study context.

2.2 Supply Chain Risk Management Strategies and the Role of Policymakers

SCRMS are employed to reduce consequences of a risk event and were originally thought of as strategies that were implemented ahead of disruptions (Fan and Stevenson, 2018). Although publications remain scarce, the COVID-19 pandemic has led to an interest in SCRMS within medicine supply chains (Scala and Lindsay, 2020; Mehrotra *et al.* 2020). For example, Yaroson *et al.* (2021) recently suggested two types of strategies for pharmaceutical supply chains: recovery (flexibility, visibility, and joint decision-making) or resistance (resource sharing). Senna *et al.* (2021) discussed the importance of mapping supply-related risk, while Hopp *et al.* (2022) suggested differentiating between mitigation (reducing occurrence) and preparedness (reducing consequences). *However, there remains a lack of empirical understanding of the differences and similarities between SCRMS implemented ahead of disruptions (normal times) versus in response to them (abnormal times).*

To explore this gap on SCRMS, we build on the seminal works by Chopra and Sodhi (2004) and Tang (2006) and use their “robust supply chain strategies” as a theoretical starting point for data collection and analysis. We further systematically review recent literature on SCRMS frameworks to assess and validate its relevance for contemporary supply chains (online supplement, Appendix D).

Table 2.1 Research framework for mapping of SCRMS

INSERT TABLE 2.1 ABOUT HERE

Based on our review, we note that redundancy can come in many forms beyond strategic stock. Examples include planned time buffers (Manhart *et al.* 2020) and excess capacity (Munir *et al.* 2020) in logistics activities beyond transport, such as information processing (El Baz and Ruel, 2021). Insurance (Fan and Stevenson, 2018) could also be viewed as a virtual redundancy strategy. We further note that some SCRMS can belong to more than one category. For example, flexible supply base (Tarei *et al.* 2020) could also be seen as strategic (vendor managed) inventory. Further, the SCRMS partly overlap in some circumstances; for example, establishing a strategic stock based on demand forecasts (Tarei *et al.* 2020) or scenarios (Srinivasan and Jeffrey, 2017) could be seen as speculation. Finally, our review illustrates the increasing importance of collaboration. Of the 33 papers we found that list collaboration as a standalone strategy (e.g., Ho *et al.* 2015) or as key in most SCRMS (Bygballe *et al.* 2022; El Baz and Ruel, 2021; Kilubi and Rogers, 2018), 24 were published since 2017.

We also identified three particularly relevant points from the review that highlight the need to knowledge advancement on SCRMS for normal versus abnormal times. Firstly, recent studies suggest that SCRMS can also come into effect after a disruption has occurred, such as through the reconfiguration of resources (El Baz and Ruel, 2021; Kilubi, 2016), However, there is no

consensus regarding which strategies are (or should be) used before and/or after a disruption occurs. Secondly, we identified few frameworks that explicitly differentiate between SCRMS for abnormal versus normal times. Tang and colleagues pointed out that robust logistics strategies should mitigate all types of disruption – small/normal (such as delays) and big/abnormal (such as natural disasters). Fan and Stevenson (2018) presented a different view, arguing that risk mitigation seems to be “most suitable for high probability, low impact risks [small] while risk transfer/sharing seems most appropriate for disruption risks with a low probability and high impact [big]” (p. 217).

Thirdly, most SCRMS frameworks focus on firms’ supply chains (cf. Jahre, 2017). SCRMS researchers seem to view policymaking mainly as an external risk to commercial supply chains (Manuj and Mentzer, 2008; Wagner and Bode, 2006). Darby *et al.* (2021) discussed the unintended consequences of the policymaking process on supply chain operations, arguing that government action causes uncertainty and influences the decisions of supply chain actors. Except for a few papers in crisis management (Ahlqvist *et al.*, 2020; Gabler *et al.*, 2017) and sustainability (Giannakis and Papadopoulos, 2016), the policymakers’ perspective remains under-studied (Ho *et al.* 2015; Nagai *et al.* 2021; Pournader *et al.* 2020). Only a few papers have addressed the role of policymakers in depth and/or shown that policymakers can also make a positive contribution to SCRMS. Yaroson *et al.* (2021) demonstrated how policymakers can play the role of intermediaries in coping with risk resulting from COVID-19 in pharmaceutical supply chains. Nagai *et al.* (2021) took the policymaker’s perspective in their study of HIV programming in Ghana. Tucker *et al.* (2020) compared market-based interventions and regulatory changes and concluded that redundancy regulations would be at least as efficient as market-based solutions to the shortage problem.

The present study helps close these gaps by using empirical evidence to provide more understanding of policymakers’ role in implementing SCRMS for managing risk in abnormal vs. normal times.

3. RESEARCH DESIGN

We used a multiple case study design (Yin, 2018) to explore the above-described phenomenon in its real-world context (Voss *et al.*, 2002; Yin, 2018). We followed an abductive approach and iterated between our collected data and literature (Dubois and Gadde, 2002; Kovács and Spens, 2005) to overcome the challenge of determining in advance what data would be relevant during the fast-evolving events following the pandemic.

3.1 Research Setting and Case Selection

We analyzed the paracetamol supply chain in seven countries – Belgium (BE), Ethiopia (ET), France (FR), Netherlands (NL), Norway (NO), Sweden (SE), and the United Kingdom (UK) – with each country’s SCRMS as the unit of analysis. Given the vastness of the generics market, we focused on paracetamol for palpability and tractability (Kim *et al.*, 2015); for example, to sufficiently map the supply chain and achieve comparability among countries. Paracetamol is a high-volume generic medicine that is used as both a painkiller and a fever-suppressant. It comes in multiple strengths (dosages) and formulations (tablets, oral suspension, and solutions for infusion). The most common paracetamol product is the 500 mg tablet. Figure 3.1 depicts a generic paracetamol supply chain, both before and during the pandemic, and is based on our analysis of the seven countries’ supply chains.

INSERT FIGURE 3.1 ABOUT HERE

Figure 3.1 General supply chain map for 500 mg. paracetamol tablets

Paracetamol is interesting for our study because it is a representative generic product used worldwide, both in high- (Wastesson *et al.* 2018) and low/middle-income countries (Kabba *et al.* 2020; Mayora *et al.* 2018; Sillo *et al.* 2018). Paracetamol is on the World Health Organization's Essential Medicine List and is necessary for treatment of COVID-19 patients. Demand for paracetamol increased by 111 percent in Germany during the first six months of 2020 (Enners *et al.* (2021) and similar results were reported for Portugal (Romano *et al.*, 2021). At the start of the pandemic, numerous sources reported paracetamol shortages for specific formulations, but some did not (AESGP, 2020; Stephens *et al.* 2020). Despite its widespread use and importance, there has been limited research on paracetamol supply chains, except for some in the last four years (cf., Enners *et al.* 2021; Kabba *et al.*, 2020; Kefale and Shebo, 2019; Mayora *et al.*, 2018; Romano *et al.* 2021; Schiavetti *et al.* 2018; Sillo *et al.*, 2018; Tujo and Gurmu, 2020).

We provide a predominantly European perspective and incorporate one low-income country. We used a combination of theoretical and criterion sampling (Patton, 2002). For theoretical sampling, we included countries of different market sizes to increase generalizability: France and the UK are large markets; Sweden, the Netherlands, and Norway are small; and Belgium is of medium size (EFPIA, 2021). For criterion sampling, we selected these six countries because they had reported significant shortages of generic drugs prior to the pandemic (Olivier, 2021) but ultimately avoided paracetamol shortages. The larger sample of European countries was necessary for contextualization because research on Europe is generally lacking (Pauwels *et al.* 2014; EFPIA, 2020; de Vries *et al.* 2021). Ethiopia's selection was partially based on convenience; it was the only low-income country within a multi-country research project. That said, Ethiopia has one of the largest medicines markets in Africa and produces some generics, offering useful contrasts to the high-income European countries. Researchers' presence and language skills allowed us to collect secondary and interview data in all relevant languages). Due to a lack of standards in reporting (Beck *et al.* 2019; Olivier, 2021; Troein *et al.*, 2020), we are not comparing countries with regard to the number or duration of shortages. Table 3.1 displays contextual differences and similarities.

Table 3.1 Supply chain context pre-COVID-19 in the seven countries

INSERT TABLE 3.1 ABOUT HERE

As shown in Table 3.1, two main distribution models are in use: direct-to-pharmacy (DTP) and multi-channel systems (Leth *et al.* 2019). In DTP, the manufacturing company assumes the marketing authorization holder (MAH – those with a license to sell) role and contracts a logistics service provider that distributes their product to all potential distribution points. In multi-channel systems, a wholesaler purchases the products from the manufacturing company and assumes the MAH role. This results in multiple wholesalers providing the same product. Finished product paracetamol manufacturers may be based in Europe, but they often offshore or outsource manufacturing to low-cost countries. Belgium, France, the UK, and Ethiopia have local production facilities. Ethiopia also receives paracetamol from donors or private suppliers.

3.2 Research process and data collection

Figure 3.2 illustrates the abductive research process that we followed, in line with Kovács and Spens (2005).

INSERT FIGURE 3.2 ABOUT HERE

Figure 3.2: The abductive research design

Based on the review of pre-COVID-19 literature, we established prior theoretical knowledge that we used as a basis for exploring SCRMS before and during COVID-19 (step 0). When the pandemic hit, we carried out an initial explorative review (Step 1) to capture what each of the case countries did to avoid shortages prior to and during the pandemic, collecting secondary data from stakeholder websites, industry-specific news outlets, general news outlets and other sources. A total of 185 secondary sources were used, some of which helped to contextualize the countries and their experiences. This first explorative review resulted in an expansion of the key stakeholder lists and the refined the research scope; that is, paracetamol as a representative generic medicine. In addition to the word “paracet*”, search terms included supply chain, stock, inventory, shortage, transport, border closure, port, trade restriction, stockpile, and emergency reserve to find sources that described potential supply chain problems and SCRMS. In Step 2, we systematically reviewed academic literature to ensure rigor and replicability (Tranfield *et al.*, 2003), searching Web of Science (WoS) and PubMed databases for studies on paracetamol, medicine shortages, SCRMS frameworks and SCRMS. We used the results to design the tools to collect and populate data in excel spreadsheets (Step 3). In Step 7, these initial searches were updated with more recent literature on frameworks, and we added searches on policymakers’ roles in SCRMS or managing risk in medicine supply chains more generally (see Online Supplementary Material, Appendix D).

The data collection phase was followed by mapping the paracetamol SC for each country. In Step 4 we sought to address the data availability challenges hampering SCM research on adverse events (Kim *et al.*, 2015; Melnyk *et al.*, 2014) by analyzing reliable secondary data sources, using those findings to develop our interview questions. We conducted 44 semi-structured interviews between October 2020 and May 2021. Respondents were from the public and private sectors located at local (such as hospitals and pharmacies), regional (such as procurement specialists), national (for example, regulatory authorities and manufacturers), and global levels (multinational companies, for instance). A common interview guide was developed, tested through pilot interviews, and revised accordingly (online supplement, Appendix C1). The interviews were conducted to capture any additional SCRMS that were not reported in the secondary sources, triangulate findings from the secondary sources, and develop a better understanding of the role of policymakers as a key stakeholder in the development or implementation of the SCRMS. Regarding policymakers, of interest is whether they have any involvement in the implementation of the SCRMS and determining what that entails.

3.3 Data analysis

We conducted both within- and cross-case analyses. For the within-case analysis, we analyzed the data per country and developed high-level supply chain maps for paracetamol. The data were recorded in a pre-structured Excel workbook, which was periodically adjusted as new themes emerged from the secondary data and the interviewee accounts. To ensure consistency across the case countries, all data collectors used a standardized template (arrived at through several iterations) for case description and a study log to document the process and findings in each country. They started with secondary data and then, where applicable, completed the

analysis using interview data. As interview data supplemented secondary data, in some of the cases the number of interviews incorporated into the analysis was curtailed once saturation was reached. For example, four out of twenty interviews were ultimately used for the UK, most of which had multiple organizations or individuals as respondents. For the cross-case analysis, we combined the populated spreadsheets per country into a single table that captured the context pre-COVID-19, (potential) shortage problems and SCRMS before and during COVID-19, and whether policymakers had direct involvement in the SCRMS employed. These tables helped us discern similarities and differences between countries on key dimensions, such as distribution models and strategies used to mitigate shortages. In this way, we qualitatively assessed the key relationships vis-à-vis SCRMS, policymakers' roles and averting shortages in normal and abnormal times. The full details of the within- and cross-case analysis procedures are presented in the online supplement (Appendix B).

4. ANALYSIS AND RESULTS

Table 4.1 summarizes our key findings of SCRMS implemented before (labelled "Pre") and/or during the pandemic (labelled "Dur"), hence capturing both normal and abnormal times, respectively. The column "public actors' involvement" captures instances where our data showed that the policymakers were actively part of the strategy implementation. The corresponding data sources are available in the online supplement (Appendix A).

Table 4.1 Identified SCRMS and their operationalization in decisions linked to policymakers

INSERT TABLE 4.1 ABOUT HERE

The results show that all the identified strategies implemented pre- and during COVID-19 could be categorized according to the framework in Table 2.1, demonstrating that it is suitable for mapping shortage management strategies in medicine supply chains. In terms of the policymakers' role, we find differences in when policymakers became involved in the implementation of operationalized SCRMS with some doing so pre-COVID-19 and others only after the pandemic struck (such as allowing foreign packages, centralizing procurement, and monitoring consumption and/or availability). Disregarding these differences among countries, we found that policymaker's involvement during normal times was mostly related to economic incentives (ET, SE, UK), strategic stock (primarily having it in place) (BE, FR, NO, UK) and some aspects of collaboration (mainly monitoring consumption/availability) (BE, FR, NO, SE, UK). During abnormal times, some operationalized strategies were carried over from normal times (for example, dual/multiple sourcing (NO) and allowing foreign packages (SE)) while some countries implemented some operationalized strategies for the first time (such as prioritizing transport (BE, ET, FR, NO, SE) and increasing safety stock (BE, NL)).

4.1 Operationalization of SCRMS Across Countries

We identified a total of 33 implemented strategies before and/or during COVID-19. Economic supply incentives, flexible supply base, and collaboration had the most operationalizations (that is, operationalizations of each of the SCRMS categories). The same strategy could be characterized in different ways depending on the level at which it was implemented or the primary purpose of implementation. An example of the former is that the re-packing and re-labelling implemented by many countries during the pandemic could be classified as speculation if it was done at the import level (FR) or as postponement if done in the pharmacy (SE, NO). Examples of the latter include the classification of staggering tendering (UK) as a SCRMS for achieving a flexible supply base and increasing maximum price (NO) as revenue

management. Arguably, these are more about contracting and economic supply incentives, respectively.

Our analysis indicates that only the UK implemented some specific SCRMS before the pandemic including prioritizing transport, joint planning/decision-making, and material and product purchases. During the interviews, this was confirmed to be primarily due to preparations for a no-deal Brexit. We identified the fewest strategies for Ethiopia and found it to be unique from the other countries in the following ways. Firstly, apart from sharing (scarce) resources, the public authorities were directly involved in all collaboration activities. Secondly, we found that Ethiopia was the only country that did not have a system for monitoring consumption before the pandemic. However, one was quickly set up for monitoring availability during the pandemic.

4.2 SCRMS and the Role of Policymakers

In general, collaborative strategies were the most commonly deployed efforts to avert shortages during the pandemic (Table 4.1). Policymakers were involved in all collaborative strategies except for the sharing of (scarce) resources. Most supply chain actors, notably hospitals, made arrangements among themselves, with little to no policyholder involvement. During our interviews, it was suggested that Norwegian Regional Health Authorities (RHAs) who own multiple hospital pharmacies could have used dormant regulations, allowing the transfer of medicines between entities that have same owner. This was not possible at the community pharmacy level due to EU Falsified Medicine Regulations (LMI, 2019). The RHAs also maintain independent emergency stocks that can be utilized accordingly (Lovdata, 2021a; b). In line with extant literature, we also identified instances where collaboration served as a catalyst or enabler for other SCRMS. One example is coordination to speed up checks and approval processes, which enabled silent product rollovers in the UK. All countries, apart from Ethiopia, used dynamic assortment planning as a SCRMS in response to downstream hoarding. This was done through rationing supply and educating downstream customers about hoarding impact. However, we could not find any tangible evidence in our data of direct involvement by the policymakers. What was evident is that dynamic assortment planning was more easily implemented if there were existing safety-related regulations to limit the maximum number of packages one customer could buy at a time (NO, SE, UK). Downstream suppliers tightened these restrictions during the pandemic. Alternatively, or additionally, the industry led the calls for rationing and later received government backing (in SE, for example).

Flexibility of the supply base via dual/multiple sourcing was found in all countries apart from France. Our data suggest that policymakers were not involved in implementing this strategy before the pandemic (BE, ET, NL, NO, SE, UK). At best, some countries indirectly influenced the behavior of supply chain actors to achieve this flexibility. For example, the UK stimulated competition by reducing the entry barriers for wholesalers (but not manufacturers). We found that, during the pandemic, Norway was the only country in which policymakers were involved in improving the flexibility of the supply base through multiple sourcing (Table 4.1).

Policymakers did not implement most of the operationalized SCRMS, but they had an influence on the supply chain actors who did. For example, at the request of the government, UK-based manufacturers scaled up production in cases of a no-deal Brexit. Ethiopian policymakers were found to contribute to make (instead of buy) SCRMS by stimulating local production through significant investments, even incentivizing foreign direct investment.

4.3 SCRMS for normal vs. abnormal times

Although multiple SCRMS were in place pre-COVID, we found limited evidence that they were specifically intended for coping with risks for abnormal times. Strategies such as including

supplier volume commitments in contracts, centralized procurement, and substitution appear to have been meant to mitigate what some respondents referred to as “business-as-usual supply risks” in normal times. Whereas some of these strategies were beneficial during the pandemic, they were not scaled for potential pandemic needs. For example, volume commitments would be insufficient for guaranteeing access to potentially unprecedented volumes.

Due to Brexit, the UK was more prepared for medicine shortages prior to the pandemic than other countries, having already implemented strategies including flexible regulatory frameworks, staggered tendering (to keep more suppliers in the market), freedom of pricing by wholesalers supplying primary care providers, and multiple sourcing.

Despite the convergence to the research framework with respect to the overall implemented SCRMS, we found widespread divergences regarding *when* the countries implemented the strategies. Apart from the UK, all countries implemented most SCRMS in response to COVID-19. The SCRMS also tended to be collaborative in nature or costly to implement. Countries further differed in that some implemented them well before any shortage occurred, while others implemented them when shortages became imminent (such as allowing foreign marking and banning parallel import). This appears to be linked to differing risk and resource levels.

5. DISCUSSION AND RESULTING CONCEPTUAL FRAMEWORK

Our study aimed to answer two research questions: (1) Which SCRMS were in place before COVID-19 to reduce generic medicine shortage and which came in place during the pandemic; and (2) What role did policymakers play in employing or adopting SCRMS? Although we found that similar SCRMS are adopted across countries, there were differences regarding (i) whether they were adopted in normal times, abnormal times, or both; and (ii) whether policymakers had some involvement in their implementation. We also found that collaborative SCRMS were mostly adopted during the COVID-19 pandemic and are unique in that policymakers worked directly with supply chain actors in search of solutions rather than seeking to influence their behavior. We now discuss our findings relative to the extant literature.

5.1 Policymakers role in (ab)normal times – a conceptual framework

Our analysis shows that policymakers played different roles in normal and abnormal times, making different decisions about their involvement in the employment of different SCRMS. There were SCRMS implemented by supply chain actors without the involvement of policymakers in both normal times (dynamic assortment planning and flexible manufacturing) and abnormal times (for example, most flexible manufacturing process and make-and-buy strategies). The following SCRMS were consistently adopted with policymaker involvement, both in normal and abnormal times: collaboration, centralization, make-and buy, speculation, silent product rollover, and postponement (Table 4.1). For collaborative SCRMS, there was a clear trend towards policymaker involvement in abnormal times, with sharing of (scarce) supplies being the exception, for which we found no evidence. The least variation among countries was found in relation to economic supply incentives, flexible supply contracts, and revenue management. This may, in part, be because there were few countries for which we found evidence of their implementation. If implemented, policymakers were involved and, in all instances, this was in normal times. We found dynamic assortment planning and flexible manufacturing processes to be implemented only in abnormal times, but with no evidence of tangible policymaker involvement.

In Section 2, we concluded that the SCRMS literature has downplayed the policymakers’ role and we set out to understand this role better. Starting with the SCRMS for which we found

evidence of policymakers’ involvement (Table 4.1), we now seek to develop richer insights on the relevance for avoiding shortages in (ab)normal times. Compared to Tokar and Swink (2019), who discussed direct versus indirect *effects* of policymaking, suggesting emphasis on policymakers’ *unintended* effects, we are interested in policymakers’ intentions (that is, *intended* effects) in the implementation of SCRMS. Thus, we focus on indirect versus direct *roles* of policymakers. We draw on research in the field of economics to distinguish between direct and indirect contributions of policymakers. Specifically, literature on environmental policies (Swaney, 1992) differentiates between policymakers’ (i) command-and-control policies that regulate behavior private actors *directly*, and (ii) market-based policies that *indirectly* influence behavior (change), through incentives. Examples of (i) include bans, technology standards, performance standards, and penalties for non-compliance, while (ii) includes taxes, fees, charges, pricing, subsidies, and tradeable permits (Sterner and Coria, 2012). These categories seem to align with our findings whereby all involvement by policymakers is a result of the intention to either regulate behavior directly (such as banning parallel imports and other regulations) or indirectly through incentives (such as economic supply incentives). However, we further found some involvement to transcend the goal of influencing behavior. Particularly during COVID-19 (and pre-COVID-19 in the UK because of Brexit preparations), policymakers worked alongside supply chain actors to seek solutions to supply issues. This applies to the bulk of collaborative SCRMS we found, lending support for the argument that collaboration is a stand-alone SCRMS (Ho *et al.* 2015). In addition, collaboration uniquely allows policymakers and supply chain actors to jointly seek solutions in abnormal times coming into play in many of the other SCRMS too.

We combine these insights and the findings in Table 4.1 to develop a conceptual framework of policyholders’ direct and indirect roles in (ab)normal times (Figure 5.1). To improve generalizability, our framework excludes strategies that were solely informed by Brexit preparations in the UK, as this was arguably an abnormal event, but not related to the pandemic. The proposed framework shows strategies adopted in both normal and abnormal times, as well as directly and indirectly by the same or different countries. It adds a third dimension (row three) compared with theory (Swaney 1992; Sterner and Coria, 2012) on direct policymaker role through joint risk management with supply chain professionals.

Figure 5.1 Policymakers’ roles in SCRMS in (ab)normal times

INSERT FIGURE 5.1 ABOUT HERE

5.2 SCRMS in normal versus abnormal times

Our findings and framework (Figure 5.1) offer important insights regarding the role of policymakers in normal and abnormal times. Firstly, we found that few policymakers implement market-based policies that provide *economic incentives* for suppliers, and all do so in normal times. Given that such policies often stimulate competition and responsiveness of supply chains (Ghadge *et al.*, 2013; Tang, 2006a; Tarei *et al.*, 2020; Tummala & Schoenherr, 2011), the question arises as to why they are so limited in their application. One possible explanation relates to additional costs that policymakers would rather avoid (as suggested by the command-and-control policies that curtail prices). However, with so few adopters, it is also worthwhile establishing the implications of adopting such policies in normal times for shortage avoidance in abnormal times.

Secondly, the relaxation of command-and-control policies both in normal and abnormal times suggests that most regulations are not geared towards improving supply risk mitigation but concerned with safety or controlling costs. This may reflect the unintended effects that Tokar and Swink (2019) referred to. As some of these measures should rightly emphasize safety over supply, it is also crucial to establish how policymakers can navigate such tensions.

Thirdly, we observe that policymakers adopt more of the same strategies when they transition from normal to abnormal times (such as allowing foreign packages). Although this reflects the suitability of those strategies for both normal and abnormal times (for example, monitoring consumption and availability), another question to ask is whether this reflects a lack of (necessary) creativity in dealing with supply issues. Are there strategies whose early adoption in normal times could lead to path dependency, i.e., a situation whereby previous strategies influence or determine response options available in abnormal times, which limits the exploration of better (for example, cheaper) alternatives?

6. CONCLUSIONS, IMPLICATIONS, AND FURTHER RESEARCH

This paper links SCRM with medicine supply chains to provide an understanding of policymakers' roles in avoiding generic medicine shortages. Using a research framework grounded in prior SCRM literature, we mapped and compared SCRMS in the paracetamol supply chains of seven countries before and during the COVID-19 pandemic. We found that all identified SCRMS could be categorized according to the framework, thereby demonstrating that SCRM can be a useful lens through which key issues in medicine supply chains can be teased out and addressed. We found varying degrees of implementation across the seven countries, both before and during the pandemic. Our study demonstrates that the same strategies can be used at different times to achieve different goals. Hence, traditional SCRM strategies are used both in normal and abnormal times.

We found that policymakers had implemented numerous SCRMS before COVID-19, but that few, if any, were intended to mitigate risks that a pandemic would pose on medicine supply chains beyond the obvious risk of change in demand. However, despite this general lack of preparedness when the pandemic struck, by doing more of the same – adapting, and if needed, being willing to activate last resort strategies (unaligned to previous strategies) – they successfully avoided shortages. The public health measures used to control the spread of COVID-19 also positively contributed to this end since, due to social distancing, improved hand hygiene, and other measures, there were fewer instances of other infectious diseases, such as the common cold or flu (Blix and Høye, 2021).

6.1 Contributions and practical and social implications

Our main contribution is the development of a better understanding of the state of the art in shortage risk mitigation strategies by policymakers in medicine supply chains. We contribute to prior literature by bridging three knowledge gaps. *We provide empirical insights demonstrating the differences and similarities between SCRMS, both before and after a disruption occurs. By extension, we show how SCRMS are implemented in normal and abnormal times. In addition, we extend the scope of SCRM by demonstrating how policymakers (can) use them to contribute to successful risk mitigation by supply chain actors.*

We also offer insights for future considerations in risk mitigation for normal and abnormal times. By linking those strategies to a SCRMS framework and refining insights through incorporating research from environmental policy research, we uncover the different ways in which policymakers can influence supply chain actors' behavior, either through command-and-

control or market-based policies. Our results suggest a third option of joint risk management between policymakers and supply chain professionals. Our research shows three trends when comparing strategies implemented in normal versus abnormal times in the context of the COVID-19 pandemic. Firstly, strategies implemented pre-pandemic were used with greater intensity during the pandemic; that is, *more of the same*. Secondly, pre-pandemic strategies were sometimes dropped in exchange for others during the pandemic, suggesting that *adaptation* had taken place. For example, many of the countries that had strategic stocks pre-pandemic switched to material and product purchases during the pandemic. This may reflect the difficulty of building stocks under high supply uncertainty and demand surges, as well as the limits of strategic stocks compared to changes in demand. Thirdly, while some strategies were not reported as implemented pre-pandemic, they were intended for implementation whenever the supply situation would become desperate. In other words, they were *last resort strategies* that tend to lie dormant until such time that they are needed. Examples include the relaxation of buying regulations and allowing foreign packages to circulate in the lower tiers of the supply chain.

Given the pessimistic forecasts that future pandemics may have on medicine supply chains, it is important that policymakers re-examine policies accordingly. The fact that paracetamol shortages were ultimately averted during the first two waves of COVID-19 demonstrates that trade-offs and use of SCRM thinking may help identify a suitable portfolio of strategies for their countries. Our second contribution of extending SCRM to how policymakers (can) use the strategies provides a pathway for how they can intervene (indirectly and directly).

In terms of practical and social implications, policymakers in the healthcare sector can use our framework and findings when developing preparedness and response plans and thinking about how they can be used in combination. The insights developed can help improve the availability of generic medicines in (ab)normal times and offer guidance to policymakers regarding (a) how to influence the behavior of supply chain actors to achieve specific goals, and (b) how and when to engage with supply chain actors to jointly seek solutions to unprecedented challenges. The results can support improvements in medicine supply chains by adding to our understanding of what is causing shortages and how such causes and their consequences can be mitigated.

6.2 Limitations and further research

In addition to the questions raised in Section 5.2., this research has limitations for future research to address. Firstly, paracetamol is a high-volume generic medicine that is available both over-the-counter and by prescription. Our findings would probably differ if we had focused on an injectable antibiotic with a smaller market, fewer producers, and stringent prescribing guidelines.

By exploring multiple countries, we found evidence that offers richer insights into two key issues, but also raises questions for future research. In particular, we found support for the contradictory claims/findings that, on one hand, no changes in regulations were required in response to supply issues caused by the pandemic (e.g., AESGP, 2020), but that, on the other hand, there were multiple adaptations of regulatory procedures to generate supplier flexibility during the pandemic (e.g., Harland *et al.*, 2021). Though our findings are more nuanced, our data do not allow us to explain why some countries avoided shortages with minimal regulatory changes, while others had to drastically adapt theirs to achieve the same result. In part, this may be caused by differences in the studied countries' healthcare systems, e.g., in terms of, ownership and density of distribution points, payment schemes and insurance as well as whether countries have national production or not. There are major differences between the European systems and the Ethiopian system drastically differs from the rest. Accordingly, we call for further research into how such differences in healthcare systems can lead to different SCRMS

in response to the same crisis (see Dube *et al.* 2022). We also identified instances where strategies like monitoring, which are viewed as a separate step in the SCRM process (Fan and Stevenson, 2018), became an integral part of SCRMS for avoiding shortages. We observed similar effects, with safety regulations being helpful for enabling dynamic assortment planning through rationing. However, we are not able to address the general question of how and under what conditions, for example the healthcare system in general, specific policies can be leveraged or repurposed for improving risk management in ab(normal) times. Hence, we call upon further research to address this key issue, similarly with recent developments in general SCRM research (Cohen *et al.* 2022).

Another issue is that even though the environmental policy research proved useful for conceptualizing policymakers' efforts to influence behavior in a supply chain context, SCRMS like collaboration do not easily fit this framework and require further exploration. We label them as joint risk management strategies in Figure 5.1, but view this as a working label. Furthermore, emerging policy responses like lengthening expiry dates (Cundell *et al.*, 2020) and modifying practices (MacArthur *et al.*, 2021) have been linked to strong path dependencies (Beck *et al.*, 2019), which can have unforeseen effects. Thus, we join the call for OSCM research to expand our existing theory toolkit (Craighead *et al.*, 2020; Harland *et al.*, 2021) to understand policymakers' roles and related outcomes ((un)intended and realized) from normal to abnormal times and back. To this end, we suggest combining economics and environmental policy research with systems perspectives within OSCM as a promising avenue.

Finally, while we found that the studied countries successfully avoided paracetamol shortages during COVID-19, there are still open questions about trade-offs with regards to cost, flexibility, and risk. Are some combinations of strategies inherently better than others or are there contingencies, like path dependency, upon which outcomes depend? Further research is needed to address such questions.

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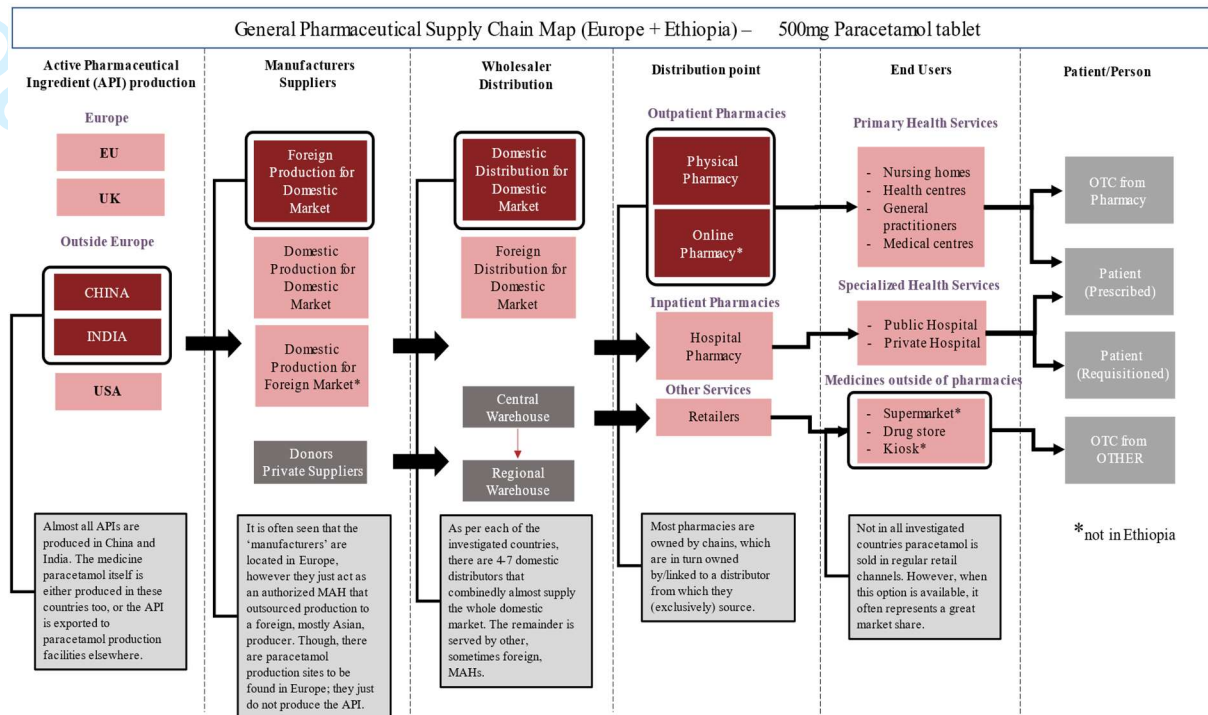


Figure 3.1 General supply chain map for 500 mg. paracetamol tablets

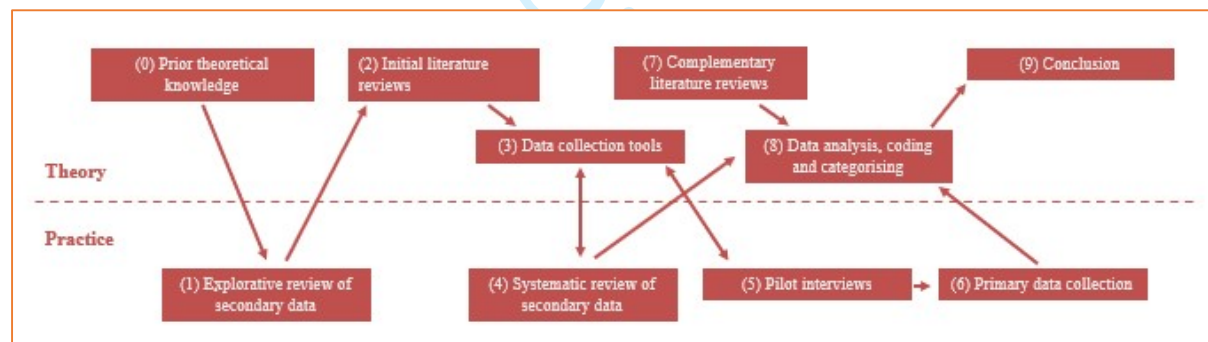


Figure 3.2: The abductive research design

	Normal	Abnormal
Indirect (Market Based)	<ul style="list-style-type: none">• Rotating market share• Lessening of price controls• Volume commitment in contracts• Agreements to allow order quantity adjustments	<ul style="list-style-type: none">• Dual/ multiple sourcing• Prioritize transport (subsidize/pay more)
Direct (Command and Control)	<ul style="list-style-type: none">• Allow foreign packages*• Increase maximum price*• Establishing emergency stocks (e.g., through directives to suppliers)• Centralizing procurement	<ul style="list-style-type: none">• Regulatory flexibility (e.g., for buying or selling)*• Allow foreign packages*• Streamline processes (regulations)• Centralizing procurement• Banning parallel exports
Direct (Joint Risk Management)	<ul style="list-style-type: none">• Improve information sharing/communication• Monitoring consumption and/or availability• Coordination to speed up checks and approval processes	<ul style="list-style-type: none">• Streamline processes (monitoring)• Improve information sharing/communication• Joint planning/decision-making• Monitoring consumption and/or availability

* Relaxation of command-and-control policies

Figure 5.1 Policymakers' roles in SCRM in (ab)normal times

Table 2.1 Research framework for mapping of SCRMS

Strategy	Explanation and examples	Authors
Centralization	Stocks, production, distribution	Jahre, 2017; Lavastre <i>et al.</i> 2014; Tarei <i>et al.</i> 2020
Collaboration	Risk sharing, supplier development, information sharing	Ahlqvist <i>et al.</i> 2020; Birkel & Hartmann, 2020; Chang <i>et al.</i> 2015; Chaudhuri <i>et al.</i> 2020; El Baz & Ruel; 2021; Fan & Stevenson, 2018; Ghadge <i>et al.</i> 2012; Ghadge <i>et al.</i> 2013; Jahre, 2017; Kilubi, 2016; Kilubi & Rogers, 2018; König & Spinler, 2016; Lavastre <i>et al.</i> 2014; Manhart <i>et al.</i> 2020; Munir <i>et al.</i> 2020; Ritchie & Brindley, 2007; Sáenz <i>et al.</i> 2018; Senna <i>et al.</i> 2021; Simangunsong <i>et al.</i> 2012; Srinivasan & Jeffrey, 2017; Talluri <i>et al.</i> 2013; Tang, 2006b; Tarei <i>et al.</i> 2020; Tummala & Schoenherr, 2011
Dynamic assortment planning	Can be used to influence choice and demand, and to entice customers to purchase products that are widely available when certain products are facing supply disruptions	Simangunsong <i>et al.</i> 2012); Tang, 2006a; b; Tarei <i>et al.</i> 2020
Economic supply incentives	Encourage additional suppliers to stay or enter into a certain market in order to avoid monopolistic situations, and to secure multiple sources should a disruption occur	Ghadge <i>et al.</i> 2013; Tang, 2006a; Tarei <i>et al.</i> 2020; Tummala & Schoenherr, 2011
Flexible manufacturing process	Allow for adjustments in quantity and quality produced in their network; for example, varying between plants and/or production lines	Chopra & Sodhi, 2004; El Baz & Ruel, 2021; Kilubi, 2016; Kilubi & Rogers, 2018; Kleindorfer & Saad, 2005; Lavastre <i>et al.</i> 2014; Manhart <i>et al.</i> 2020; Sáenz <i>et al.</i> 2018; Simangunsong <i>et al.</i> 2012; Sodhi & Tang, 2012; Srinivasan & Jeffrey, 2017; Talluri <i>et al.</i> 2013; Tang, 2006; Tang & Tomlin, 2008; Tarei <i>et al.</i> 2020
Flexible supply base	Multiple sourcing options available, thus allowing for alternatives should one source be disrupted. One way of doing this is to develop a supply alliance network with suppliers in various countries; this is also called hedging.	Birkel & Hartmann, 2020; Chang <i>et al.</i> 2015; Chopra & Sodhi, 2004; Ghadge <i>et al.</i> 2012; Ghadge <i>et al.</i> 2013; Jahre, 2017; Kilubi, 2016; Kilubi & Rogers, 2018; Kleindorfer & Saad, 2005; Knemeyer <i>et al.</i> 2009; Lavastre <i>et al.</i> 2014; Manhart <i>et al.</i> 2020; Munir <i>et al.</i> 2020; Manuj & Mentzer, 2008; Simangunsong <i>et al.</i> 2012; Srinivasan & Jeffrey, 2017; Talluri <i>et al.</i> 2013; Tang, 2006a; b; Tang & Tomlin, 2008; Tarei <i>et al.</i> 2020; Tummala & Schoenherr, 2011
Flexible supply contracts	Agreements with suppliers allowing the customer to adjust order quantities depending on need	Birkel & Hartmann, 2020; Chopra & Sodhi, 2004; Fan & Stevenson, 2018; Ghadge <i>et al.</i> 2012; Ghadge <i>et al.</i> 2013; Jahre, 2017; Kilubi, 2016; Kilubi & Rogers, 2018; Manhart <i>et al.</i> 2020; Manuj & Mentzer, 2008; Simangunsong <i>et al.</i> 2012; Sodhi & Tang, 2012; Srinivasan & Jeffrey, 2017; Tang, 2006; Tang & Tomlin, 2008
Flexible transportation	Multi-modality, multiple carriers and/or multiple routes	Birkel & Hartmann, 2020; Chopra & Sodhi, 2004; Kilubi 2016; Jahre, 2017; Kilubi & Rogers, 2018; Kleindorfer & Saad, 2005; König & Spinler, 2016 ; Lavastre <i>et al.</i> 2014; Manhart <i>et al.</i> 2020; Srinivasan & Jeffrey, 2017; Tang, 2006a, Tarei <i>et al.</i> 2020
Make-and-buy	Combination of in-house and outsourcing, which allows more flexibility in case of a disruption. Includes vertical integration	Chopra & Sodhi, 2004; Ghadge <i>et al.</i> 2013; Jahre, 2017; Kleindorfer & Saad, 2005; König & Spinler, 2016; Manuj & Mentzer, 2008; Simangunsong <i>et al.</i> 2012; Tang, 2006a; Tarei <i>et al.</i> 2020
Postpone-ment	Utilizes product or process design concepts such as standardization, commonality, modular design, and operations reversal to delay	Ghadge <i>et al.</i> 2012; Ghadge <i>et al.</i> 2013; Kilubi, 2016; Jahre, 2017; Kilubi & Rogers, 2018 ; König & Spinler, 2016; Manuj & Mentzer, 2008; Munir <i>et al.</i> 2020;

	the point of differentiation in products, services, movement and other value-adding activities.	Sáenz <i>et al.</i> 2018 ; Simangunsong <i>et al.</i> 2012; Tang, 2006; Tang & Tomlin, 2008; Tarei <i>et al.</i> 2020
Revenue management	Dynamic pricing and/or promotion	Chopra & Sodhi, 2004; Simangunsong <i>et al.</i> 2012; Tang, 2006; Tang & Tomlin, 2008; Tarei <i>et al.</i> 2020
Silent product rollover	'Leak' new products into a market without making formal announcements	Tang, 2006; Tang & Tomlin, 2008; Tarei <i>et al.</i> 2020
Speculation	Opposite of postponement, such as forward placement of inventory, forward buying and early commitment to the form of a product	Birkel & Hartmann, 2020, Fan & Stevenson, 2018; Manuj & Mentzer, 2008; Manhart <i>et al.</i> 2020; Munir <i>et al.</i> 2020; Srinivasan & Jeffrey, 2017; Tarei <i>et al.</i> 2020
Strategic stock	Inventories at certain 'strategic' locations (warehouses, logistics hubs, distribution centers) that can be deployed quickly in case of a disaster. Often shared by multiple supply chain partners, such as vendor-managed inventory.	Chang <i>et al.</i> 2015; Chopra & Sodhi, 2004; Ghadge <i>et al.</i> 2012; Ghadge <i>et al.</i> 2013; Jahre, 2017; Kilubi, 2016; Knemeyer <i>et al.</i> 2009; König & Spinler, 2016 ; Lavastre <i>et al.</i> 2014; Manhart <i>et al.</i> 2020; Simangunsong <i>et al.</i> 2012; Talluri <i>et al.</i> 2013; Tang, 2006a; Tarei <i>et al.</i> 2020

Table 3.1 Supply chain context pre-COVID-19 in the seven countries

Distribution points	Health-care provider		Pharmacy		Retailer
	BE, ET, FR, NL, NO, SE, UK		BE, ET, FR, NL, NO, SE, UK		ET, NL, NO, SE, UK
Distribution models	Multi-channel system		Direct to pharmacy		
	BE, FR, NL, NO, UK		BE, SE		
Regulated stock-/safety stock-levels	Framework agreements on supply, penalty regulated		Framework agreements on safety stock		1–6 months depending on product
	FR, SE, UK		NL		NO
National shortage monitoring	BE, ET, FR, NL, NO, SE, UK				
Publicly available information on shortages	List of current shortages	List of historic shortage registrations	Serious shortage protocols	Limited shortage protocols	Information in health commodity information system & platform
	BE, NL, NO, SE	NO, SE	UK	FR	ET

Table 4.1 Identified SCRMS and their operationalization in decisions linked to policymakers

What SCRMS	HOW SCRMS - Operationalized	SCRMS			Countries with evidence of SCRMS (BE, ET, FR, NL, NO, SE, UK)
		Implemented		Public actors' involvement?	
		Pre	Dur		
Dynamic assortment planning	Rationing at consumer level		✓		BE, FR, NL, NO, SE, UK
	Educating downstream customers about hoarding impact; asking them not to hoard		✓		BE, FR, NL, NO, SE, UK
Economic supply incentives	Rotating market share through tendering process (keep more suppliers in the market)	✓		Yes	SE

	Lessening of price controls (e.g., freedom of pricing by suppliers)	✓		Yes	UK
	Volume commitment in contracts	✓		Yes	SE, UK
	Investment incentives for foreign manufacturers	✓		Yes	ET
Flexible manufacturing processes	Scalability (including in factory or process design)	✓			UK
			✓		FR, UK
	Increasing repurposing (including in factory or process design)		✓		BE, UK
Flexible supply base	Increasing local production	✓			ET
	Dual or multiple sourcing	✓			BE, ET, NL, NO, SE, UK
			✓	Yes	NO
	Staggering tendering (e.g., regional)	✓			UK
	Regulatory flexibility (buying out of license)	✓	✓	Yes	UK
Flexible supply contracts	Agreements to allow order quantity adjustments	✓		Yes	BE
Flexible transportation	Prioritize transport (modes) (e.g., subsidize/pay more)	✓		Yes	UK
			✓	Yes	ET, BE, FR, NO, SE, UK
Make-and-buy	Domestic manufacturing and imports (e.g., by wholesalers)	✓			ET, UK
	Increase share of domestic production compared to exports	✓			ET, FR
			✓		FR
	Relaxation of buying regulations		✓	Yes	UK
Postponement	Decoupling API bulk contracts to postpone product-to-market allocation	✓			BE
		✓		Yes	SE
	Allowing foreign packages*		✓	Yes	NO, SE
Revenue management	Increasing maximum price	✓		Yes	NO
Silent product rollover	Substitution	✓			BE, NO, SE, UK
			✓		FR, UK, SE
	Streamlined processes (e.g., granting licenses, monitoring)		✓	Yes	SE, UK
Strategic stock	Establishing emergency/strategic stocks	✓		Yes	BE, FR, NO, UK
	Increase safety stock (e.g., manufacturer, distributors, and wholesalers) to cope with greater uncertainty		✓		BE, NL
Centralization	Centralizing procurement	✓		Yes	NO, UK
			✓	Yes	SE
	Centralizing strategic/buffer stock	✓			UK
			✓		SE
Collaboration	Improve information sharing/communication	✓		Yes	BE
			✓	Yes	FR, ET, SE, UK
	Joint planning/decision-making	✓		Yes	UK
			✓	Yes	ET, SE, UK
	Sharing (scarce) supplies		✓		ET, NL, UK
		✓			NL
	Monitoring consumption and/or availability	✓		Yes	BE, FR, NO, SE, UK
			✓	Yes	ET, SE
Speculation	Coordination to speed up checks and approval processes (e.g., suppliers and product quality)	✓		Yes	ET, UK
		✓			UK
	Material & product purchases		✓		BE, NL, NO, SE, UK
	Banning parallel exports		✓	Yes	NO

Appendix A: Research process and Data collection

This study was motivated by the results of a proceeding study by de Vries *et al.* (2021) which reviewed stakeholder reports on drug shortages from six European countries: Belgium, France, the Netherlands, Norway, Sweden, and the United Kingdom. All six were also cases in this study. In addition, Ethiopia was selected as a seventh case. Figure 3.1 illustrates the research process we followed in line with Kovács and Spens (2005). Based on a review of the literature pre-COVID, we established prior theoretical knowledge (Step 0 in figure 3.1) that we used as a basis for exploring SCRMS pre- and during COVID-19.

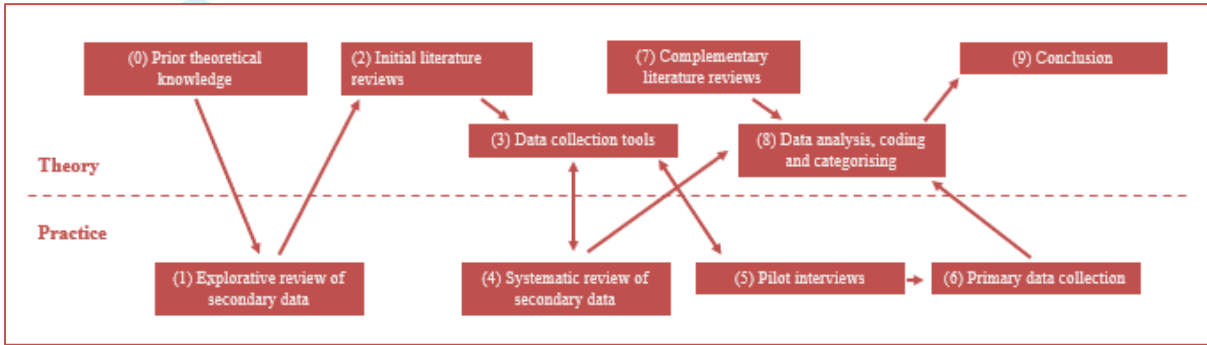


Figure 3.1: The abductive research design

When the COVID-19 pandemic hit, we carried out an initial explorative review of secondary data to capture what each of the case countries did to avoid shortages (step 1 in figure 3.1). Data sources were collected through searches on stakeholder websites, industry-specific news outlets, general news outlets and google searches. This first explorative review resulted in a list of key stakeholders and the refining of the research scope for this study, i.e., focusing on paracetamol as a representative generic medicine. Search terms included supply chain, stock, inventory, shortage, transport, border closure, port, trade restriction, stockpile, and emergency reserve to find sources that described potential supply chain problems and interventions, from here on termed SCRMS - Supply Chain Risk Management Strategies. Weekly searches were conducted from March 2020 to June 2020. We thoroughly read the documents and analysed their contents in an excel sheet based on the conceptual framework we had developed for the mapping.

In Step 2 of the study, initial literature reviews were conducted. This included a systematic search and review of the academic literature to ensure rigour and replicability (Tranfield *et al.*, 2003). We restricted our search to peer-reviewed academic articles written in English. We stored all relevant articles with publication details of each: authors, year, title, and journal. In the first round, we searched Web of Science (WoS) and PubMed databases for studies on paracetamol, medicine shortages, and SCRMS frameworks. We used the results from that literature review to design the tools to collect and populate data in excel spreadsheets (step 3 in figure 3.1). These initial searches were updated with more recent literature (step 7 in figure 3.1) on SCRMS frameworks (published after our data collection), literature on medicine shortages (published after the pandemic hit) and paracetamol shortage (both academic and grey literature published after our data collection). In this second round, we added searches on policymakers' roles in SCRMS or managing risk in medicine supply chains more generally. The updates were deemed necessary due to the increased research output on both medicine shortages and SCRMS resulting from the pandemic. The updates helped to further refine the data analysis. After these iterations we ended up with four central review streams (See details below in Appendix D):

- Building on de Vries et al. (2021) approach we reviewed literature published from January 2020 to December 2021.
- Building on the approach in Jahre (2017), we reviewed papers on SCRM frameworks published from June 2016 to February 2022.
- Academic papers on paracetamol supply or shortage up to February 2022.
- Academic papers on SCRM and policymaker/public up to February 2022.

The data collection phase of this study was proceeded by mapping the paracetamol SC for each country. Thereafter, we sought to address the data availability challenges hampering SCM research on adverse events (Kim *et al.*, 2015; Melnyk *et al.*, 2014) by analyzing reliable secondary sources (grey literature) (step 4 in figure 3.1) and then using those findings to develop our interview questions. Grey literature includes a range of documents not controlled by commercial publishing organizations. «Information on applied public health research questions relating to the nature and range of public health interventions, as well as many evaluations of these interventions, may be predominantly, or only, held in grey literature and grey information. Therefore, evidence syntheses on these topics need to embrace grey literature and information» (Adams *et al.* 2016:1¹). We purposefully selected key stakeholder reports focusing on describing issues and interventions. We deliberately avoided documents on non-generics (e.g., innovative cancer medicines) or specific aspects of drug shortages (e.g., effects for patients) to stay with the general, i.e., shortages of generic drugs. The purpose was to get key stakeholders' understanding of the problem, its effects, and their SCRMS in addressing it. Firstly, the sources retrieved in the explorative review of secondary data were filtered based on the abovementioned criteria. Secondly, additional searches were done on stakeholder websites (public bodies, industry organizations and individual company websites), industry-specific news outlets, general daily news outlets. The searches were restricted to sources published between 01 March 2020 – 22 December 2020 and focused on paracet(amol). All search results were reviewed and sources that mentioned shortage, potential shortage and/or SCRMS related to this AND paracetamol (or a specific medicine with paracetamol as its active ingredient) OR indirectly relates to paracetamol were included. The search platforms together with the secondary sources are detailed in appendix A1.

Parallel to the grey literature review, we developed a common interview guide (step 3 in figure 3.1), tested through pilot interviews (step 5 in figure 3.1) and revised accordingly. The final interview guide can be viewed in Appendix C2. We conducted 45 semi-structured interviews between October 2020 and May 2021 (step 6 in figure 3.1) to fill in information gaps and triangulate them with the secondary data. An overview of the conducted interviews sorted by case country can be found in appendix C1. Data availability was a challenge in some countries, particularly regarding product demand and shortages statistics. When data was lacking or publicly unavailable, we qualitatively assessed shortages before and during the pandemic through the interview data.

Appendix A1: Search platforms and secondary sources per country

¹Adams, J., Hillier-Brown, F.C., Moore, H.J. *et al.* Searching and synthesising 'grey literature' and 'grey information' in public health: critical reflections on three case studies. *Syst Rev* 5, 164 (2016). <https://doi.org/10.1186/s13643-016-0337->

Country Stakeholder	Belgium	France	Netherlands	Norway	Sweden	United Kingdom
Ministry of Health	Government website (Federale Overheidsdienst Volksgezondheid) - www.health.belgium.be	Ministry of Health and Solidarity - solidarites-sante.gouv.fr	Government website - www.rijksoverheid.nl	Ministry of Health and Care Services - www.regjeringen.no	Ministry of Health and Social Affairs - www.regeringen.se	Ministry of Health and Social Care - www.gov.uk
Health Regulator/ Directorate	Government website (Federale Overheidsdienst Volksgezondheid) - www.health.belgium.be	Haute autorite de sante - www.has-sante.fr	Website assessment body for drugs - www.cbgmeb.nl	Norwegian Directorate of Health - helsedirektoratet.no	Socialstyrelsen - www.socialstyrelsen.se	Medicines and healthcare products regulatory agency (MHRA) - www.gov.uk
Public Health Agency	Federaal Agentschap voor Geneesmiddelen Gezondheidsproducten - www.fagg.be	Public Health France - www.santepubliquefrance.fr	Public health institute - www.rivm.nl	Norwegian Institute of Public Health - www.fhi.no	Folkhälsomyndigheten - www.folkhalsomyndigheten.se	Public Health England - www.gov.uk
Medicines Agency	Agentschap Zorg en Gezondheid - www.zorg-en-gezondheid.be	Agence Generale des Equipements et Produits de Sante - ageps.aphp.fr	Assessment body for drugs - www.cbgmeb.nl	Norwegian Medicines Agency - legemiddelverket.no	Läkemedelsverket - www.lakemedelsverket.se	
Health care provider	Belgische Vereniging der Ziekenhuizen - www.hospitals.be	Federation Hospitaliere de France www.fhf.fr	Hospital association - www.nvz-ziekenhuizen.nl	Sykehusinnkjøp - sykehusinnkjop.no	Sveriges kommuner och Regioner - skr.se	
Additional public bodies – Health care			Monitoring body for pharmacists - farmanco.knmp.nl	National Center for Medicine Shortages and Preparedness in Specialist Health Service - oslo-universitetssykehus.no	Tandvård- och läkemedelsförmånsverket - www.tlv.se Ehalsomyndigheten - www.ehalsomyndigheten.se	
Additional public bodies – Health care associations					Försvarets forskningsinstitut - www.foi.se Sveriges riksdag - www.riksdagen.se Myndigheten för skydd och beredskap - www.msb.se Riksrevisionen - www.riksrevisionen.se	

Industry organisations & news outlets		Orde National des Pharmaciens - www.ordre.pharmacien.fr	Association for new drugs - www.vereniginginnovatiev Eugeneesmiddelen.nl Association for pharma wholesalers - vno-ncw.nl	Association of the Pharmaceutical Industry in Norway - www.lmi.no Norwegian Pharmacy Association - www.apotek.no Pasientforeningen - www.pasient.no Kreftforeningen - kreftforeningen.no	Sveriges Farmaceuter - www.sverigesfarmaceuter.se Läkemedelshandlarna - www.lakemedelshandlarna.se Sveriges Apoteksförening - www.sverigesapoteksforening.se Generikaföreningen - www.generikaforeningen.se Apotekssocieteten - www.apotekarsocieteten.se Sveriges läkarförbund - slf.se Läkemedelstidningen - lakartidningen.se Dagensmedicin - www.dagensmedicin.se Lif - www.lif.se Läkemedelsvärlden - www.lakemedelsvarlden.se DN - www.dn.se DI - www.di.se Sveriges Radio - sverigesradio.se Svenska Dagbladet - www.svd.se	Association of the British pharmaceutical Industry - www.abpi.org.uk Bio Industries Association - www.bioindustry.org Association of British Healthcare Industry - www.abhi.org.uk Organisation supporting the biomedical, pharmaceutical and life sciences sectors across the North of England - www.bionow.co.uk British in Vitro Diagnostics Association - www.bivda.org.uk European Federation of pharmaceutical Industries & Associations - www.efpia.eu International Federation of pharmaceutical Manufacturers & Associations - www.ifpma.org North East of England Process Industry Cluster - www.nepic.co.uk National Institute for Health & Care Excellence - www.nice.org.uk Oxford Biotech Network - www.obn.org.uk
Individual company		Les Entreprises du Medicament - www.leem.org		Karo Pharma - karopharma.no	Tamro - www.tamro.se Oriola - www.oriola.com SKL Kommentus - www.sklkommentus.se	

Below is a list of the secondary sources reviewed for each case country. Some sources gave background information, whereas other directly addressed the issues relating to our research questions and thus serve as references in table 5.1 in the paper.

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Appendix B: Data analysis

The secondary sources retrieved in step 4 of the research process were reviewed by a data collector speaking the official language(s) of the individual case country. In total we had nine data collectors involved, some assisting each other across countries and some replacing others. The reviewers focused on identifying evidence of shortages, reasons for shortages (if any), and SCRMS to avoid a shortage situation in the grey literature. An English summary/description was documented. PDF files of sources were created to ensure traceability, and key paragraphs and citations were highlighted. A pre-structured data collection workbook that was periodically adjusted as new themes emerged from the data was populated with the findings from this review. This process served as the 1st step of coding. Each SCRMS that was identified in each data source was logged separately. For each SCRMS the following information was logged: a short description, date of reporting or announcement, expected impact, entity or person that proposed/ executed the intervention and if it was proposed or implemented. In addition to the workbook, all data collectors wrote a case description using a standardized template, developed through several iterations. The data collectors also kept a study log to document the process and findings in each country to ensure consistency across the seven case countries.

Moving into step 8 in the research process, an additional stage of coding based on the conceptual framework was undertaken to categorize findings (see Table 2.1). This analysis was done separately for each country in a standardized excel sheet as exemplified in appendix B1. The data collectors were asked to suggest new SCRMS categories if they could not fit within the existing framework. By doing so we opened for the data to adopt the pre-defined conceptual framework. If a data collector suggested a new category for SCRMS, this was communicated to the rest to minimise duplication and overlap.

The coding by each data collector was then checked by a fellow data collector who spoke the language. We subsequently combined the populated excel workbooks per country to create an overview of each

country context pre-COVID, (potential) shortages and related concerns, and SCRMS during COVID. This way, we could conduct a cross-case analysis. During this process, the suggested SCRMS for each case were discussed. Three co-authors (two of whom were not highly involved in the data collection and analysis up to this point) went through the overview and looked for unintended duplication and overlaps. After eliminating such, the ultimate result was that all strategies adopted by each country fit within the SCRMS framework that was used to guide the study, i.e., no new SCRMS were identified.

Appendix B1: Within case analysis – Illustrative example of 2nd stage of coding

The table shows the analysis for Norway. The same was done for all case countries. During the analysis phase the table also included a column for comments to ensure transparency on coding and provide additional contextual information to assist the three co-authors who consolidated the analyses and conducted the cross-case analysis. As these were internal notes, sometimes with follow-up comments, they are not shown in the table.

Country		Norway		Secondary Sources	Interview Source(s)
Shortage - Normal (N), More than normal (>N), less than normal (<N), concerns for more than normal (P), No shortage (No)		P		N/A	N/A
What was the cause? (Demand, Supply, Market, Production, Medical)		Demand			P30, P33, P34, P35
What were the concerns i.e., the potential causes that was not actualised? (Demand, Supply, Market, Production, Medical)		Demand, Supply, Market, Production			P23, P26, P27, P28
SCRMS		Interventions Pre-Covid	Changes to interventions/ new interventions during Covid	Secondary Sources	Interview Source(s)
If no shortage, was it due to interventions 2020?	Dynamic assortment planning	Rationing consumer level	Rationing – new legislation. See comment.	NO38	P23, P33, P34
	Economic supply incentives			N/A	N/A
	Flexible manufacturing process			N/A	N/A
	Flexible supply base	Increase supply base	Permitted parallel import of paracetamol products in 2020 and have extended it to 2022. This increased the supply base.	NO48	P33, P34, P36, P37
	Flexible supply contracts	Ban parallel export	Paracetamol was listed on a "notification list". This	NO38	P23

			means that the Norwegian Medicines Agency must be notified three working days before a planned parallel export		
	Flexible transportation		Privately hire planes to bring in paracetamol from India or China		P26
	Make-and-buy			N/A	N/A
	Postponement	Allow foreign marking		NO48	
	Revenue management			N/A	N/A
	Silent product rollover	Substitution		NO44	P31, P27
	Strategic stock	Framework agreement with wholesalers	The health authorities entered into an agreement with the three major pharmaceutical wholesalers on expanding the emergency stocks of pharmaceuticals critical for use in the public health service.	NO16	P26, P28, P30, P31, P32, P33, P34, P35, P36, P37, P38
	Centralization	Procurement			P26
	Collaboration	Monitoring shortages		NO37	P23, P24, P25, P26, P27, P28, P29, P33, P34, P35, P36, P37
	Speculation			N/A	N/A
Other - if interventions are difficult to categorize, please add here and explain					

Appendix C: Interviews

C1: Interviews by country

Country	Identifier code	Affiliation
Belgium	P1	Private organisation, global
	P2	Private organisation, global
Ethiopia	P3	Public organisation, federal
	P4	Public organisation, federal
	P5	Public organisation, federal
	P6	Public organisation, federal

	P7	Public organisation, regional
	P8	Public organisation, regional
	P9	Public organisation, regional
	P10	Public organisation, regional
	P11	Public organisation, regional
	P12	Public organisation, regional
	P13	Public organisation, regional
	P14	Public organisation, regional
	P15	Public organisation, regional
	P16	Public organisation, regional
	P17	Public organisation, regional
France		No interview sources were used in the analysis
Netherlands	P21	Private organisation, national
	P22	Private organisation, local
Norway	P23	Private organisation, national
	P24	Private organisation, national
	P25	Public organisation, national
	P26	Public organisation, national
	P27	Public organisation, national
	P28	Public organisation, national
	P29	Organisation funded by public & private, national
	P30	Private organisation, national
	P31	Private organisation, national
	P32	Public organisation, national
	P33	Private organisation, global
	P34	Private organisation, global
	P35	Private organisation, global
	P36	Private organisation, global
	P37	Private organisation, global
	P38	Public organisation, regional
Sweden	P39	Private organisation, national
	P40	Private organisation, national
	P41	Public organisation, national
	P42	Public organisation, national
	P43	Private organisation, global
	P44	Private organisation, national
United Kingdom	P48	Public organisation, national
	P53	Public organisations, national
	P54	Private organisation, national
	P61	Public organisation, regional

C2: Interview guide

1. Can you describe what your organization does in normal times and in case of crises when it comes to medicine supply (e.g., COVID-19)?
 - a. In the supply chain ranging from manufacturers to patients/consumers, where is your organization and which stakeholders do you interact the most with? [Show supply chain map that we drew]
 - i. Do you think this pharmaceutical supply chain draft correctly represents the current chain?
 - ii. Where do you think bottlenecks occurred in the supply chain (if they did) during COVID19? Was this a change compared to pre-COVID?
 - iii. How is information shared among stakeholders? How efficient / quick is it? Do you think there is a better way? If so, why in your opinion isn't it changing?
 - b. What kind of supply chain decisions does your organization make (e.g., placing orders, managing stock levels, transporting medicines, setting prices)?
 - c. Does your organization have a specific role/assignment in connection to medicines shortages?
2. Can you describe your role in your organization?
 - a. Which part of the supply chain (we talked about in the previous question) are you focused on (e.g., placing orders, managing stock levels, transporting medicines, setting prices)?
 - b. What kind of decisions do you make with respect to this part of the supply chain?
3. What actors do you consider to be central for the national medicines supply?
 - a. Could you comment on this map of the paracetamol supply chain(s) – does it reasonably reflect the supply chain(s) in which you take part?
 - b. Do you have any information on stock levels, lead times (in rough numbers) and transportation modes used in the SC?
4. Was shortage (potential or actual) a problem before COVID-19? Which products in particular? If yes, could you elaborate on probable causes and what has been done to solve the problem? What did you/your organization do in this regard? What was the results/expected results from these actions?
5. Has availability of paracetamol changed (more potential or actual shortage), during COVID-19? Did you expect such changes? Why/why not?
6. In case of more (potential or actual) shortage, could you provide some notable examples, and elaborate on (probable) causes and what has been done/will be done to solve the problem?
 - a. The causes: supply/demand/distribution/market
 - b. The interventions: what did you do and how quickly did you respond? Had these interventions already been discussed in connection with improving preparedness in general, i.e., pre-COVID?
 - c. Has the problem changed during the pandemic (1st, 2nd, 3rd Wave)? Have the interventions changed?
 - d. What do you/your organization do in this regard?
 - e. What would you have done differently now that you know what happened?
 - f. What other actors have been central in this response?
 - g. What interventions affected your organization the most? Why? Do you think other organizations were affected the same way?
7. What was the most urgent change / biggest risk before the COVID (not in terms of shortage necessarily)
8. What do you consider are the challenges in managing the paracetamol supply chain with respect to securing availability at pharmacy/hospital/other outlets (i) in general and (ii) during the pandemic (waves)?
9. What would make it easier to prevent shortages? Did you become aware of any of these measures as a result of the pandemic? If so, which ones?
10. We are particularly interested in ongoing or potential cooperation between countries on supply chain relevant activities:
 - a. Joint procurement
 - b. Joint strategic stocks
 - c. Joint agreements on investment and establishment of own production
 - d. Joint transport or other agreements
 - e. Other initiatives or ideas for sharing (tangible and non-tangible) resources across countries/regions to avoid shortages?

11. What about competition? Did you experience export bans, increasing prices, discussions with other countries?
12. Is there anyone else we should speak with?
13. Any other follow-up questions that the country lead might wish to ask based on the analysis of the grey literature and the quantitative analysis of product usage /shortage data e.g., questions regarding funding, information flows, or specific interventions.

Appendix D: Review and analysis of academic literature

Review	Database	Search terms	Results
Shortage	Web of Science and Pubmed	medicin* shortage*, drug* shortage*, medicinal* shortage*, AND vaccine* shortage*	335 papers. A screening of abstracts excluded those which did not cover shortages observed, causes of shortages, effects of shortages, interventions to tackle shortages, or impact of interventions as well as those focusing on effects on patients with a weak link to the supply chain. This resulted in 14 relevant <i>new</i> papers (in addition to those reviewed in De Vries et al. (2021).
SCRM framework	Web of Science	supply chain risk management AND framework	38 papers. Abstracts, and were necessary papers, were screened excluding those that covered only specific risk types (such as price) and/or specific contexts (such as food). Articles on the pharmaceutical context were included. This resulted in 18 relevant <i>new</i> papers (in addition to those reviewed in Jahre (2017).
Paracetamol	Web of Science	paracet* AND supply* OR shortage	93 papers. We screened titles and abstracts but did not find much of relevance to our study. Most papers were concerned with pollution/waste from paracetamol production, effects on patients because of overuse or the efficacy and safety of paracetamol for pain relief. This resulted in 8 relevant papers.
SCRM and policymaker/ public	Web of Science	supply chain risk management AND policymak* supply chain risk management AND public	53+10 papers. We screened titles and abstracts, and if necessary, the papers, excluding those who only used 'policymakers' when concluding with practical implications (providing insights to policymakers) and 'risk' as a general term, not in the meaning of supply chain risk. Further, we excluded articles that only regarded public authorities and agencies or the general public in the contribution section. In total this resulted in 4+5 relevant papers.

D1: Academic literature on shortage Jan-2020-December 2022

Beck, M., Buckley, J. and O'Reilly, S. (2019), "Managing pharmaceutical shortages: an overview and classification of policy responses in Europe and the USA", *International Review of Administrative Sciences*, Vol. 86 No. 4, p. 622-640.

Benhabib, A, loughlissen, S., Ratignier-Carbonneil, C., and Maison, P. (2020), "The French reporting system for drug shortages: description and trends from 2012 to 2018: An observational retrospective study, *BMJ OPEN*

Clark, S.L., Levasseur-Franklin, K., Pajourmand, M., Barra, M., Armahizer, M., Patel, D.V., Chester, K.W. and Tully, A.P. (2020). Collaborative Management Strategies for Drug Shortages in Neurocritical Care, *Neurocrit Care*, 32, 226-237, <https://doi.org/10.1007/s12028-019-00730-7>

Cummings, K., Bexhadi, B. and Martonosi, S. (2020). Centers for Disease Control and Prevention as a Strategic Agent in Pediatric Vaccine Market: An Analytical Approach, *Manufacturing & Service Operations Management*, 1-15, <https://doi.org/10.1287/msom.2020.0902>.

Cundell, T., Guilfoyle, D.m Kreil, T.R. and Sawant, A.(2021) Controls to Minimize Disruption of the Pharmaceutical Supply Chain During the COVID-19 Pandemic, *PDA Journal of Pharmaceutical Science and Technology*, t doi:10.5731/pdajpst.2020.012021

- Evenett, S.J. (2020) Chinese whispers: COVID-19, global supply chains in essential goods, and public policy
JOURNAL OF INTERNATIONAL BUSINESS POLICY 2020
- Liu, I., Colmenares, E., Tak, C., Vest, M-H., Clark, H., Oertel, M. and Pappas, A. (2021). Development and validation of a predictive model to predict and manage drug shortages. *Am J Health-Syst Pharm.*, 78(14), DOI 10.1093/ajhp/zxab152
- Mac Arthur, R.B. , Ohad S. Bentur² , Ian C. MacArthur³ , Anna S. Bartoo⁴ , Donna L. Capozzi⁵ , Jason A. Christensen⁴ , Amber L. Johnson¹ , Kuldip Patel⁶ and Barry S. Colle (2021) CTSA pharmacies: Contribution to research and public health during the COVID-19 pandemic, *Journal of Clinical and Translational Science* 5: e108, 1–7. doi: 10.1017/cts.2021.13
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- Vinchi, D. L., Polidori, P., Milkovic, Batista, A., Amann, S., Makridaki, D. and Kohl, S. (2021) Lessons learnt from the COVID-19 pandemic: results of EAHP survey on the future crisis preparedness of hospital pharmacies, *Eur J Hosp Pharm*, doi:10.1136/ ejhpharm-2021-002944

Paper	Comparing interventions	Own data on root causes of shortage	Systems perspective	Policymaker role
Beck et al. (2019)	Develop typology of policies incl. level of action (individual product level/therapeutic level/active ingredient level), time frame (from ad hoc/short term to long term) and strategic approach reactive/ mitigating/preventive). Compare EU, US, Germany, Spain, Austrian, Ireland.	NA.	Characterize shortage as systems shock	YES
Benhabib et al. (2020)	Analyse drug shortages in France 2012-2018. Drugs on shortage were mostly old products (63.4%) with national marketing authorisation procedures (62.8%), as well as injectable and oral forms (47.5% and 43.3%, respectively). Anti-infectives for systemic use ranked first (18%), followed by nervous and cardiovascular system drugs and by antineoplastic and immunomodulating agents (17.4%, 12.5% and 10.4%, respectively). The number of reported shortages presented a fourfold increase between 2012 and 2018 and a sharp rise in 2017 and 2018, along with a rise in the number of active substances on shortage.	NA	NA	NA
Clark et al. (2020)	Strategies discussed: adjustment in staffing models, implementing restricted use criteria, alternative administration strategies, procuring alternative preparations, allow temporary use of non-formulary alternatives, centralizing supply and provision of therapeutic substitution policies.	NA	NA	Review institutional mitigation strategies in response to drug shortage.
Cummings et al. (2020)	Minimize negotiated government cost while ensuring adequate supply.	NA	Combine optimization and game-	How government can ensure

			theoretic techniques.	cost-effective procurement of vaccines: financial incentives, product differentiation, ongoing negotiations.
Cundell et al. (2020)	Discuss effectiveness of strategies to minimize disruptions from COVID-19. Suggest use of risk analysis tools including staff recruitment, procurement of API and packaging, facility design and operation, cleaning and protections, manufacturing, packaging/labelling, warehousing, shipment, dispensing, patient usage.	Mention increased demand.	Discuss direct and indirect risks from COVID-19	Conclude with regulatory responses such as lengthening expiration dates,
Evenett (2020)	Since the beginning of 2020, 91 jurisdictions are reported executing a total of 202 export controls, 105 jurisdictions reported executing 228 import policy reforms of medical supplies and medicines.	Refer to FDA on reasons for drug shortage September 2020. 'What is significant about these findings is that the root causes of medicine shortages are not blamed on cross-border supply chains but are much more complex in nature'	Looks at trade flows.	Evaluate policy interventions for medical and food trade by France, Germany, the United Kingdom, and the United States in 2020.
Liu et al. (2021)	Change the drug shortage management strategy from a reactive process to a more proactive approach using predictive data analytics.	Predictors that positively predicted shortages included classification of drugs as intravenous-only, both oral and intravenous, antimicrobials, analgesics, electrolytes, anesthetics, and cardiovascular agents. Predictors that negatively predicted a shortage included classification as an oral-only agent, branded-only agent, antipsychotic, Schedule II agent, or orphan drug, as well as the total number of manufacturers.	Use of predictive analysis.	NA
Mac Arthur et al. (2021)	Survey to pharmacy departments on how shortages were managed during COVID-19.	NA	NA	Discuss pre- vs. modified COVID-19 practices.
Milanesi et al. (2020)	Review literature on sustainability of pharmaceutical supply chains.	NA	NA	NA
Miljkovic et al. (2020a)	Study European Hospital Pharmacists' perceptions of need for risk assessments.	NA	Call for multi-stakeholder communication.	NA
Miljkovic et al. (2020b)	Study use of risk assessment in European countries. Find little use of systematic assessments.	NA	Call for multi-stakeholder communication.	Conclude with lack of legal instruments for assessments.
Musazzi et al. (2020)	Based on the scores obtained in the constant part of the algorithm, decision trees for risk-management strategies (i.e. variable part of algorithm) can be built up according to the features of different settings (e.g., manufacturers, wholesalers, hospitals, pharmacies) or National regulatory frameworks.	Discuss EMAs root cause analysis. Refer to the EMA harmonized procedure for measuring shortage impact on patient health.	Mentions ripple effect.	Review the current European regulatory framework on medicine shortages
Shukar et al. (2021)	Divide management strategies into management of current shortages, improvement in operations, and changes in governmental policy (policies and program changes; advance notification system,	Discuss causes classifying into demand, supply and regulatory. Nothing on root causes.	NA	Point to inflexible regulatory processes, lack of policies and

	guidelines, uniform shortage definition pricing and expedited drug review). No empirical data.			communication among stakeholders.
Vinci et al. (2020)	Report on shortages experienced during covid by surveying hospital pharmacies. Find that therapeutic substitution, additional strategic stock, borrowing from other hospitals, extra import and generic substitution were used to mitigate.	NA	NA	NA

D2: Academic literature on SCRM frameworks Jun 2016-Feb 2022

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D3: Academic literature on paracetamol

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D4: Academic literature on SCRM and policymaker

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D5: Academic literature on SCRM and public

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