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ORIGINAL ARTICLE

Drug shortages: A systems view of the current state

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ABSTRACT

The objective of this thought leadership article is to create a systems view of drug shortages based on the perceptions of practitioners and policymakers. We develop a comprehensive framework describing what stakeholders are currently doing when faced with drug shortages and show the outcomes of their actions. In a review of practitioner literature and public reports published from 2010 to 2020, we identify cause-and-effect relationships related to generic drug shortages in six high-income European countries (Belgium, France, the Netherlands, Norway, Sweden, and the UK) in normal times. By combining and connecting data from these different sources, we develop a systems view of the current state. Though several of the associations covered in the systems view are well known, putting them all together and considering their interrelationships is what is offered by this research. Based on this systems view, we derive three basic solution archetypes for drug shortages: (1) let the market handle it; (2) search for alternatives; and (3) bend the rules. The interactions between these archetypes generate causal ambiguity making it harder to understand and solve the problem as the side effects of solutions can be missed. We show how the interaction of archetypes can compromise intended behavior or escalate unintended behavior. However, our systems view allows us to suggest higher-level solution archetypes that overrule such side effects. The basic and higher-order solution archetypes can provide baselines for research and support the development of future interventions.

KEYWORDS
drug shortage, feedback loops, supply chain management, systems view

1 | INTRODUCTION

Drug shortages are a growing worldwide issue, despite advancements in manufacturing, distribution, and transport technologies (Phuong, Penm, Chaar, Oldfield, & Moles, 2019). Shortages can have severe consequences for patients and healthcare providers. They can lead to mortality, treatment changes, inferior treatment, and medication errors (McLaughlin et al., 2013; Phuong et al., 2019). In 2019, 56% of US hospitals reported they had changed patient care or delayed therapy due to drug shortages, while almost 37% said they had rescheduled planned or emergent procedures. A recent study among 2136 hospital pharmacies in 39 European countries revealed that 95% consider medicine shortages to be a problem (EAHP, 2019).

Stakeholders and researchers grappling with drug shortages recognize that the problem largely originates in the design, management, and governance of drug supply chains (De Weerdt, Simoens, Hombroeckx, Casteels, & Huys, 2015; Heiskanen, Ahonen, Kanerva, Karttunen, & Timonen, 2017; Pauwels, Huys, Casteels, & Simoens, 2014). Supply chain causes are also emphasized in reports from the European Association for Hospital Pharmacists (EAHP, 2019), the European Federation of Pharmaceutical Industries and Associations (EFPIA, 2020), and the US Food and Drug Administration (FDA, 2019).

In addition to the problems described in the literature, our research was motivated by interactions with key stakeholders of drug supply chains in Norway. A risk scenario analysis conducted by the Norwegian Directorate for Civil Protection concluded that drug shortages together with pandemics are the most serious threats to Norwegian societal security, both in terms of probability of occurrence and consequences (DSB, 2019). During the fall of 2019, we discussed the problem with senior executives and managers of, among others, the Norwegian Institute of Public Health, the Norwegian Medicines Agency, the Norwegian Directorate of Health, and the Norwegian Pharmacy Association. These conversations revealed that drug shortages, particularly for generics,[1] are frequent, even in high-income countries like Norway. One stakeholder noted that "*a research project focused on drug shortage is important for public health and preparedness*," while another mentioned that it is important to study "*the differences between short- and long-term effects of shortages and understanding the decisions made by supply chain actors*." Appendix S1 provides more information about these conversations. Our interactions with practitioners and policymakers laid the groundwork for an international, publicly funded research project about shortages of generic medicines beginning in 2020. This article is one of the outputs.

Taking stock of stakeholders' understanding of drug shortages in high-income countries is the first important step to addressing this problem: It allows one to "listen to practitioners" (Wickert, Post, Doh, Prescott, & Prencipe, 2021) and to define relevant academic research questions. We, therefore, performed a review of documents and reports, also termed gray literature (Adams et al., 2016), published in six European countries. We deliberately chose gray rather than academic literature to create a map of *stakeholders*' understanding by systematically synthesizing *their* reports on cause-and-effect relationships related to shortages. Certainly, stakeholder documents might be colored by specific agendas. However, they capture stakeholders' perceptions of how the current system works. These perceptions influence actions, policies, and the behavior of the system. We identified three groups of stakeholders: industry actors (e.g., drug manufacturers and wholesalers), healthcare providers (such as hospitals and pharmacies), and policymakers (e.g., ministries of health and health regulators). We deliberately excluded documents published after 2019 to discount COVID-19-induced effects, because we wanted to capture "normal" times.

Our review reveals that stakeholders primarily suggest actions or solutions that may work well for one drug in one country (so-called first-order effects), without discussing the potential side effects of these solutions for other drugs and/or actors in other countries (so-called higher-order effects). We find that actions can be categorized into three basic solution archetypes: (1) let the market handle it; (2) search for alternatives; and (3) bend the rules. The first archetype entails interventions and decisions made by industry actors to solve drug shortages. The second captures decisions made by healthcare providers and medical experts to offer "workarounds." The third archetype represents decisions made by policymakers and regulatory bodies to stimulate or even force industry actors to help solve the problem by changing rules.

The public reports show little evidence that stakeholders are aware that these basic solution archetypes interact with each other, not only within one country but also between countries. It may be dangerous to treat them independently, as side effects may not be recognized. We categorize these side effects into two groups: archetypes eliciting "compromising system behavior," and archetypes eliciting "escalating system behavior." Compromising system behavior resembles an arms race between two countries; for example, when countries start stockpiling while supply is constrained. Escalating system behavior happens when a basic solution archetype backfires because of an unintended side effect. For instance, health policymakers may opt for more transparency in the supply chain. But when industry actors (e.g., wholesalers) have a better view of when and where shortages occur, they may start hoarding earlier, which increases demand and supply instability (bullwhip effects).

By putting together the pieces from numerous stakeholders in six countries, we discover interdependencies that would not reveal themselves if we had looked at individual countries or a single drug only. This is exactly the key contribution of this article: based on the available "fishbones" (first order, mostly linear, effects often shown in Ishikawa diagrams) from the public reports, and combining the results for generic drugs from six countries, we weave a "fishing net" (a systems view of drug shortages). Based on our systems view, we suggest two higher-order solution archetypes. Our approach allows us to derive research propositions and future research questions for our community that can lead to more impactful research (Holmström, Ketokivi, & Hameri, 2009).

We position our work as a thought leadership article using a unique approach to develop knowledge on the drug shortage topic. Our broad, international perspective on the drug shortage problem warrants a comprehensive listing of cause-and-effect relationships in different operational contexts and economic situations in different countries. It is not an empirical theory-testing study, we do not compare the performance of different countries on the metric of shortages, nor do we assess the quality of the documents included in our review. Instead, we review practitioner literature and public reports with the aim of developing a high-level understanding of the current state of shortages as perceived by pharmaceutical and healthcare industries and policymakers—their reactions to shortages and the implications of those reactions. As such, our article has the potential to shape the conversation and perhaps even the paradigm of researchers.

[1] A pharmaceutical product usually intended to be interchangeable with the originator brand product, manufactured without a license from the originator manufacturer, and marketed after the expiry of patent or other exclusivity rights. (https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf)

2 | LITERATURE REVIEW

Drug shortages are a global concern and increasing access to drugs is a complex issue (WHO, 2018). We define drug shortages as "a period of time when the demand or projected demand for the drug […] exceeds the supply of the drug" (FDA, 2019, p. 4). In recent years, several researchers and stakeholders have studied the causes. Heiskanen et al. (2017) stressed the small size of the pharmaceutical market, sudden or fluctuating demand, small stock sizes, long delivery times, and long or complex production chains. Pauwels et al. (2014) noted economic reasons, while De Weerdt et al. (2015) pointed at quality regulations. Production problems and quality concerns have also been mentioned as causes (Pauwels et al., 2014; Tucker, Daskin, Sweet, & Hopp, 2020). This increased interest in drug shortages is also present in the gray literature. The FDA listed three root causes of drug shortages: a lack of incentives to produce less profitable drugs, a lack of recognition and rewards for mature quality management systems, and logistical and regulatory challenges that make it difficult for the market to recover after a disruption (FDA, 2019). The EFPIA published its own list of causes, most of them originating in supply chains (EFPIA, 2020).

Yet, few studies have focused on the possible interrelationships between causes of shortages and solutions: how one cause could lead to another, or how trying to prevent a cause may give rise to another. In addition, most academic research seems to focus on a single country, type of stakeholder, or drug (e.g., Heiskanen et al., 2017; Woodcock & Wosinka, 2013; Yurukoglu, Liebman & Ridley, 2017), which is understandable given requirements for rigor in addressing narrowly defined questions. The result is that the literature focuses primarily on first-order causes and effects of drug shortages. Studies examining causal interrelations (higher-order) are particularly scarce, both in the academic and gray literature (De Vries, Jahre, Selviaridis, Van Oorschot, Van Wassenhove, 2021).

Because drug supply chains are interconnected systems involving multiple countries and drugs, actions that mitigate one risk can end up exacerbating another (Chopra & Sodhi, 2004). For example, drug shortages in "normal" situations are believed to result from multiple decisions, events, and interactions by many distinct actors, including pharmacies, health facilities, suppliers, manufacturers, regulatory bodies, and patients (De Weerdt et al., 2015; Pauwels et al., 2014). It is important for decision-makers to understand these interrelationships and to abandon linear models (Plsek & Greenhalgh, 2001). The problem of drug shortages is systemic and requires higher-order, system-level perspectives.

Systems thinking is the ability to see the world as a complex, dynamic system in which everything is connected to everything else (Sterman, 2000). Dynamic complexity arises from cause-and-effect interactions of agents over time. System performance or behavior emerges as a nonlinear and dynamic function of a large number of activities conducted in parallel by interacting entities (Basole & Bellamy, 2014; Nair, Narasimhan, & Choi, 2009; Pathak et al., 2007). Because of the tight couplings among actors, actions feed back on themselves, creating feedback loops. In a feedback ("closed-loop") view of the system, change is seen as arising from the endogenous interactions of decision-makers with their environment (Sterman, 1989). Here, there are no single root causes. With a few exceptions (e.g., Cohen, 2017; Jalali, Rahmandad, Bullock, Lee-Kwan, Gittelsohn, & Ammerman, 2019; Kochan, Nowicki, Sauser, & Randall, 2018; Mahamoud et al., 2013), the application of methods to analyze feedback loops in public health is a nascent phenomenon that requires further development (Carey, Malbon, Carey, Joyce, Crammond, & Carey, 2015; Chughtai & Blanchet, 2017).

Studies of decision-makers' causal attributions or mental models show that few incorporate any feedback loops. Instead, people tend to formulate decision trees, root cause analyses, or fishbone (Ishikawa) diagrams relating possible actions to probable consequences (De Langhe, Puntoni, & Larrick, 2017; Sterman, 1994). Thus, EFPIA (2020) has called for "all relevant sources of information to be used in order to provide additional intelligence about the root causes and drivers of shortages" (p. 4). The quest for root causes of drug shortages exemplifies a linear or "open-loop" view.

However, as drug supply chains are strongly interdependent and complex systems, it may be impossible to identify such "root" or initiating causes. For example, the FDA presents three root causes in their report (FDA, 2019), but cites "contributing factors" in their explanation. These contributing factors are, in fact, causes of the root cause. For instance, lack of transparency across the supply chain appears as a contributing factor to the root cause "lack of recognition and rewards for mature quality management systems." Trying to find the starting point in a supposed linear causal chain (first-order analysis) is not wrong, but it is a job half done, as interdependencies and feedback loops (higher-order analysis) are ignored.

Our research uses linear causal chains, identified by stakeholders in generic drug supply chains from different countries, to assemble a higher-order, systems view of drug shortages. We further examine how this systems view helps in understanding and solving drug shortages. Because different stakeholders tend to identify only a few pieces of the puzzle, we need this broad scope of analysis to capture as many pieces as possible. Our article is unique in using such a broad collection of practitioners' knowledge to create a systems view of drug shortages.

3 | METHODS

We focus on generic drugs because they are particularly susceptible to shortages, as price-based competition after the expiration of patents significantly reduces profitability and market attractiveness (Pauwels et al., 2014; WHO, 2016). In addition, supply chains for generic drugs share many common characteristics. For example, many have low buffer capacity (inventory and production) in their supply chains, long lead times, and multiple manufacturers. Focusing on one drug and its supply chain would be too narrow a scope to reveal higher-order interrelations between causes and effects within and across countries.

3.1 | Scoping review

We performed a scoping review of the gray literature (i.e., publicly available policy reports, governmental communications, and press articles) on drug shortages across six countries. Scoping reviews are frequently used in health research (Pham et. al., 2014) to clarify the conceptual boundaries of a topic and to provide an overview of evidence (Munn, Peters, Stern, Tufanaru, McArthur, & Aromataris, 2018; Tortorella, Fogliatto, Vergara, Vassolo, &, Sawhney, 2020). They help in identifying and mapping key concepts that underpin a research topic, especially when it has not been reviewed comprehensively before (Mays, Roberts, &, Popay, 2001; Peterson, Pearce, Greig, Sargeant, Papadopoulos, &, McEwen, 2017). Compared with a systematic literature review, a scoping review is less likely to address very specific questions (Munn et al., 2018), or to assess the quality of included studies (Arksey & O'Malley, 2005) because it aims to provide a more comprehensive overview of available literature. A scoping review does not focus on the relative weight of evidence in favor of any particular intervention. The key strength of a scoping review is that it can illustrate the field of interest in terms of the volume, nature, and characteristics of the primary research. This analysis in turn makes it possible to identify the gaps in the evidence base, as well as summarizing and disseminating findings, so that policymakers, practitioners, and consumers are better placed to make effective use of the findings (Arksey & O'Malley, 2005). Because we aim to develop a systems view of the current state of drug shortages, as perceived by pharmaceutical and healthcare industries and policymakers, we believe the scoping review is an appropriate method for our research.

3.2 | Stakeholder selection and screening

By collecting data from different countries, we account for contextual factors that might be different, but also connected in the European or even global system. Important interrelations may be hard to detect from a single-country perspective. In our scoping review, we included Belgium, France, the Netherlands, Norway, Sweden, and the UK (Appendix S2 provides information on contextual similarities and differences between these countries). We deliberately opted for a European perspective, because the publicly funded research project this article belongs to is about Europe, and because research on Europe is scarce (EFPIA, 2020; Pauwels et al., 2014). To find relevant stakeholders in each country, we consulted the latest risk analysis documents published by ministries/governmental agencies, or other equivalent publications to identify their sources. We examined the website of the Ministry of Health (or equivalent) in each country. This also helped us identify additional key stakeholders: public health agencies, healthcare providers, manufacturers, wholesalers and distributors, and patient representative organizations. Initially, 80 stakeholders were identified (listed in Appendix S3). Next, we explored the websites of these stakeholders. We excluded 12 because their websites did not mention drug shortages. For the remaining 68, we performed an online search for any information related to drug shortages and published between January 1, 2010, and December 31, 2019. We excluded 2020–2022 documents from our sample because our focus is on drug shortages "in normal times," and we wanted to avoid such atypical influences as COVID-19 or Brexit. Our search led to almost 11,000 hits in the six countries, related to public reports. After screening and removing duplicate hits, we ended up with 135 reports produced by stakeholders in six countries. The full list of the public reports we analyzed is provided in Appendix S4.

3.3 | Data extraction and analyses

Our scoping review followed the PRISMA-ScR guidelines (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) (Tricco et al., 2018). The PRISMA-ScR flowchart (Moher, Liberati, Tetzlaff, & Altman, 2009) of search and report selection is presented in Figure 1. The 135 selected public reports were fully read with the purpose of finding cause-and-effect relationships related to drug shortages. Eventually, 65 public reports were excluded from our analysis because they did not mention cause-and-effect relationships. In the remaining 70 reports, each identified relationship was recorded and classified using a data coding scheme. To help the coding process, we selected core concepts used in scientific research to describe causes and effects related to drug shortages (see Appendix S5 for a list of these concepts; note that new concepts could be added). Cause-and-effect relationships were recorded using the following fields: description of the cause, description of the effect, specification of this relationship (positive or negative relationship, with or without a time delay), study source (reference), and country.

3.4 | Reliability

Coding and analysis of the public reports was conducted by a team of 12 researchers (including three of the authors). For each country, two researchers were assigned to code the data to ensure bias-free analysis and assessment of the document sources. We checked a sample of the coded reports to identify and discuss any coding differences. We then adjudicated those and continued. For example, a report by the National Pharmacy Association in the UK (NPA, 2018) lists obstacles to a smooth-running supply chain, such as: "*If there*

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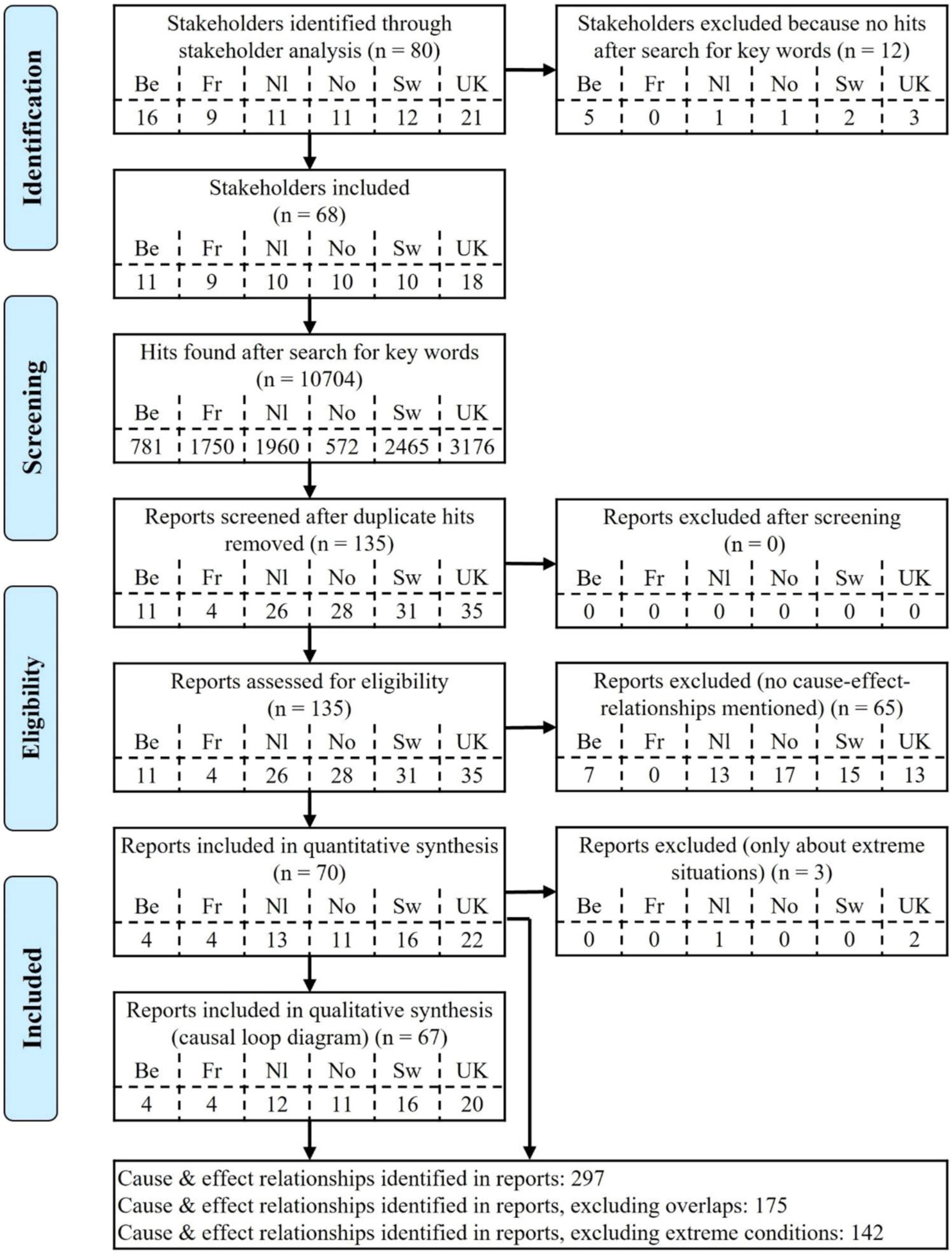

FIGURE 1 PRISMA-ScR flowchart of search and public report selection

is a problem at one of those factories, or a glitch in the transportation system, it is possible for the entire stock of particular medicines to become unavailable for months." This relationship was coded as a production/quality/distribution problem (cause) leading to a lower inventory level of drugs (effect). This link can also be found in Appendix S6, as link 9, which is based on source 65 (among other sources). In addition, during the data coding process, we held lengthy discussions and made iterations to ensure a standardized approach across the six countries. These steps increased our confidence in the reliability of our coding and analysis. The coded data from all six countries were checked by the first author (who reads all the relevant languages and was not involved in the coding process) and then merged into Appendix S6 for further analysis.

3.5 | Quantitative (linear) and qualitative (feedback) synthesis

Our search revealed 297 linear cause-and-effect relationships, which we analyzed in two steps. First, we performed a quantitative synthesis of all relationships. This includes a cross-country comparison of all identified relationships to find similarities and differences between countries. Although our research does not aim to explain such similarities and differences, they are important. When countries mention similar cause-and-effect relationships, these relationships get the same identification, that is, link number in our analysis. As such, more referrals to the same link do not add new data to our systems view of drug shortages. When countries mention different cause-and-effect relationships, these links are assigned different numbers. These differences provide new relationships to the systems view. Second, we performed a qualitative synthesis. Specifically, we connected linear relationships to each other, so that causal (feedback) loops could be discovered. Relationships activated by extreme situations (like Brexit) were included in the quantitative analysis to show that Brexit has, understandably, received considerable attention in public reports in the UK. However, as our research aims to understand drug shortages at regular times, we excluded 33 relationships we identified in three reports focusing on extreme situations from our further, qualitative analysis. The procedure we used to turn the linear view into a systems view will be explained with examples in the next section.

4 | RESULTS

4.1 | Quantitative synthesis of the linear view (cause-and-effect relationships)

Appendix S6 provides an overview of the different cause-and-effect relationships we identified, sorted by frequency. The highest possible frequency was six, meaning that all countries mentioned this relationship in their public reports. For example, all countries mentioned the positive causal relationship between "availability of raw materials" and "production volumes" (link 1 in Appendix S6). After excluding duplicates, we found 175 unique cause-and-effect relationships. Almost 38% (66) of these were found in more than one country, while the rest were mentioned by only one country (62%, or 109 unique relationships).

We derive three main findings from this quantitative synthesis. First, judging from the long list of possible causes/interventions and their effects, it is safe to assume that stakeholders are aware of the problem of drug shortages and have no trouble identifying possible causes. Second, 62% of the identified cause-and-effect relationships were mentioned by only one country. This small overlap between countries may indicate that stakeholders within each country only see or focus on specific parts (puzzle pieces) of the problem. This is not necessarily wrong, as some countries may indeed experience different problems from others. However, there is the danger of missing important cause-and-effect relationships when these are not included in stakeholders' partial views of the puzzle. For us, the relationships that were mentioned by only one country are as valuable as the overlapping relationships: Each relationship adds a piece to the puzzle. Third, stakeholders appear to have difficulty thinking one step further or deeper than a linear cause-and-effect relationship (at least they primarily report linear relationships). Specifi-

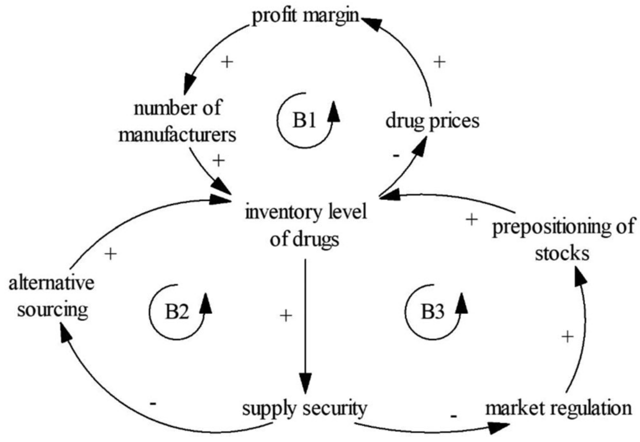

FIGURE 2 Examples of feedback loops derived from linear cause-and-effect relationships

cally, we found no mention of feedback loops in our material. For example, it was left unsaid that interventions may be counteracted by other countries, or that they may backfire in one's own country in the long term. The public reports thereby seem to exemplify a linear view of the world. The next subsection explains how we constructed a systems view.

4.2 | Qualitative synthesis of the systems view (causal loop diagram)

The next step in our analysis was to take the 142 relationships from all countries to develop a systems view and to discover feedback relationships. These can be revealed by weaving together individual, linear cause-and-effect relationships ("fishbones"). Two relationships can be woven together when a cause mentioned by one relationship is also mentioned as an effect in the other. In fact, we discovered many causal loops or feedback loops ("fishing net"). Below, we illustrate this process for three feedback loops in detail. Figure 2 depicts these loops.

4.2.1 | Balancing loop 1 (B1-loop)

Reports from the Netherlands and the UK mention that low inventory levels can drive up prices (see link 46 in Appendix S6). According to reports published in the Netherlands and Norway, higher prices can positively impact profit margins (link 42). Reports from France, the Netherlands, and Norway mention that an increase in profit margins can cause an increase in the number of manufacturers (link 31). Finally, an increase in the number of manufacturers can positively influence inventory levels according to reports in Norway, Sweden, and the UK (link 26). These relationships make a balancing loop (indicated with a B): starting with a low inventory level, higher prices and profits lead to more manufacturers and, consequently, higher inventories. Balancing loops counteract and oppose change. As such, balancing loops suggest solutions to the problem. Seen in isolation, link 26 explains that a low number of manufacturers could be the cause of a drug shortage. But together with the other three links in the balancing loop, we read that drug shortages could (partially) be solved by market mechanisms, that is: high prices increase the attractiveness of the market for manufacturers, which increases the number of manufacturers operating in this market.

4.2.2 | Balancing loop 2 (B2-loop)

Reports from three countries (France, Norway, and Sweden) mention that low inventory levels can lead to lower supply security (link 25). According to sources from the UK, this could lead to the search for alternative sources, for example, different manufacturers (link 169), and these alternative sources could in turn lead to higher inventory levels again (link 70). Taken together, these links make up another balancing loop that suggests a solution to the problem of drug shortages.

4.2.3 | Balancing loop 3 (B3-loop)

The same link between low inventory levels and a reduction of supply security (link 25) that started loop B2 can also start loop B3. Low supply security can motivate policymakers to change the rules in the market according to a report from the Netherlands (link 171). For example, it can lead to more rules for prepositioning of stocks, which is suggested in reports from the Netherlands and Sweden (link 56). Finally, reports from the Netherlands, Norway, Sweden, and the UK mention that prepositioning has a positive effect on inventory levels (link 14). A new balancing loop is formed that points to a solution. In this example, the solution is initiated by policymakers defining rules for keeping safety stocks of drugs to prevent shortages.

These three examples show that valid feedback loops can only be derived by combining findings from different countries. Focusing on France, for example, would not have provided this overview. The complete systems view consists of over a thousand feedback loops and can be found in its entirety in Appendix S7. Though it shows the interconnectedness and complexity of drug supply chains, it is also too complex to support decision-makers in choosing when and how to intervene in a drug shortage. However, by grouping similar loops, we discovered three "basic solution archetypes," as we call them.

4.3 | Three basic solution archetypes to curb drug shortages

The systems view that connects all linear cause-and-effect relationships identified in our scoping review captures not only possible causes of shortages but also solutions. For example, a low number of manufacturers could cause low inventory levels, and consequently, more drug shortages. Following these same links, any intervention that increases the number of manufacturers may have a positive impact on inventory levels and may help resolve drug shortages. Accordingly, our systems view, which is shown in Appendix S7, suggests over a thousand feedback loops that describe solutions to drug shortages. To synthesize all these feedback loops, we looked at where in the system these solutions could be activated. Therefore, we categorized the identified feedback loops into three groups of solutions for drug shortages, which correspond to three types of decision-makers: industry actors, healthcare providers/medical experts, and policymakers. Why the term "basic solution archetypes"? Archetypes represent recurring patterns of structures. They are analogous to basic sentences or simple stories that get retold again and again (Senge, 1990). Such archetypes reveal the simplicity underlying the complexity of management issues. We describe each below.

4.3.1 | Let the market handle it (B1)

Feedback loops within this basic solution archetype represent market mechanisms common to all supply chains. They include the effects of demand versus supply on drug prices, the effects of availability of raw materials on production volumes, the effects of production problems on delivery delays, and so on. When these links are connected to each other in feedback loops (as described in the previous subsection), they suggest solutions for drug shortages that can be executed by industry actors. Examples of solutions that belong to this archetype may include:

- Low inventory levels drive up drug prices (link 46). Higher prices may lead to higher profit margins for manufacturers (link 42). High-profit margins enable investments in the quality of production facilities, thereby reducing production problems (link 160), which has a positive effect on inventory levels (link 9).
- High drug prices may also increase parallel imports (link 18), which increase inventory levels (link 27). Parallel import is the practice of importing a drug from one country to repackage and sell it under the price in another country.
- Low inventory levels may lead to more sickness (link 122) and, consequently, higher demand for drugs (link 66). Faced with higher demand, manufacturers may experience more buying power vis-à-vis their suppliers (link 37), which has a positive effect on future inventory levels (link 35).

4.3.2 | Search for alternatives (B2)

The second basic solution archetype describes "workarounds" to solve a drug shortage, typically initiated by healthcare providers and medical experts. These solutions involve finding alternative drugs or alternative forms of the same drug (e.g., different dosage, pack size, or packaging with foreign labels) or even alternative manufacturers (second sources). Examples of solutions that fall within this archetype are:

- Low inventory levels can lead to a search for alternative sources of the same drug (link 169). This could be different manufacturers, or even inventories in different countries, resulting in higher inventory levels (link 70).
- Low inventory levels can start a search for alternative drugs (link 5). If allowed, replacements will reduce the inventory levels of these alternatives (link 10) but will have a positive effect on the inventory levels of the original drug (link 4).

4.3.3 | Bend the rules (B3)

Solutions belonging to this archetype explain what policymakers and regulators can do to increase inventory levels by (temporarily) changing existing market regulations and policies. For instance, procedures could be simplified and standards somewhat relaxed to reduce lead times, or rules may be enforced to increase safety stocks. Bending rules will not immediately solve the problem, but through these adjustments, policymakers and regulators can persuade or force industry actors to behave in such a way that drug shortages are resolved. For example:

- Low inventory levels lead to lower supply security (link 25). Policymakers can choose to adjust quality regulations for manufacturers, for example, expedite approvals for use of alternative active pharmaceutical ingredients suppliers and extend product expiry dates. This may reduce quality-related problems in production and distribution (link 162), which leads to higher inventory levels (link 9).
- Rules can also target drug prices. Policymakers could set higher reference prices, which positively impacts profit margins (link 164), making the market more attractive for manufacturers (link 31). This will have a positive effect on inventory levels (link 26).
- Policymakers can also demand more prepositioning of stocks (buffering; link 56). This also has a positive impact on inventory levels (link 14).

4.4 | Compromising and escalating system reactions to basic solution archetypes

The three basic solution archetypes describe relatively straightforward interventions. Seen in isolation, they help resolve drug shortages. For example, when a wholesaler in Norway has trouble reaching the far north of the country, using an alternative drug until the roads are cleared from snow may help. However, these basic solutions could also lead to additional problems when we consider how the "bigger" system may react, globally and over the long term.

Side effects of basic solution archetypes are feedback loops that are activated when one of the basic solutions for drug shortages is chosen. Our basic solution archetypes are all balancing feedback loops: they aim at counteracting changes to resolve drug shortages. Side effects can be balancing or reinforcing. When a side effect is balancing, the basic solution may have the intended effect for a short time, or on a small scale, but it also activates a reaction in the system that eventually impedes the effectiveness of the basic solution. The problem of drug shortages thus persists after implementing the basic solution. This is a *compromising system reaction* (Wolstenholme, 2003). When a side effect is reinforcing, the basic solution creates a reaction that makes the problem worse, represented by a reinforcing feedback loop (a vicious cycle). This is an *escalating system reaction* (Wolstenholme, 2003). Examples of such higher-order compromising and escalating reactions to basic solution archetypes are discussed below.

4.4.1 | Examples of compromising system reactions

Our systems view provides ample examples of interactions between basic solution archetypes that compromise each other's effectiveness. In Figure 3, we show examples of a solution belonging to one archetype activating a response in the same or another archetype.

Example A describes an "arms race" where countries are stockpiling drugs. When policymakers in Country A decide to change rules to push for more prepositioning, the intended effect is an increased inventory level of this drug. But, when policymakers in Country B find out about this, they may be tempted to copy this behavior to safeguard their share of a potentially limited supply. Thus, two "bend the rules" archetypes occurring in different countries compromise each other's effectiveness. If one country manages to get more supplies than the other, the overall problem is not solved. If both get more, there may be another country that is suffering.

Example B explains that wholesalers and other trading entities in Country B could start to export drugs to Country A, especially when Country A is willing to pay a higher price. This will increase Country A's inventory level. However, policymakers in Country B could protect their domestic market by setting up trade barriers. This example shows how a "let the market handle it" archetype activates a "bend the rules" archetype that compromises the intended effect. In the end, the problem for Country A is not solved, and Country B faces unpopular and potentially harmful trade restrictions.

Finally, Example C depicts a situation where Country A, due to an inventory shortfall, decides to temporarily buy drugs with a foreign label from suppliers in Country B. This could activate a hoarding response from wholesalers in

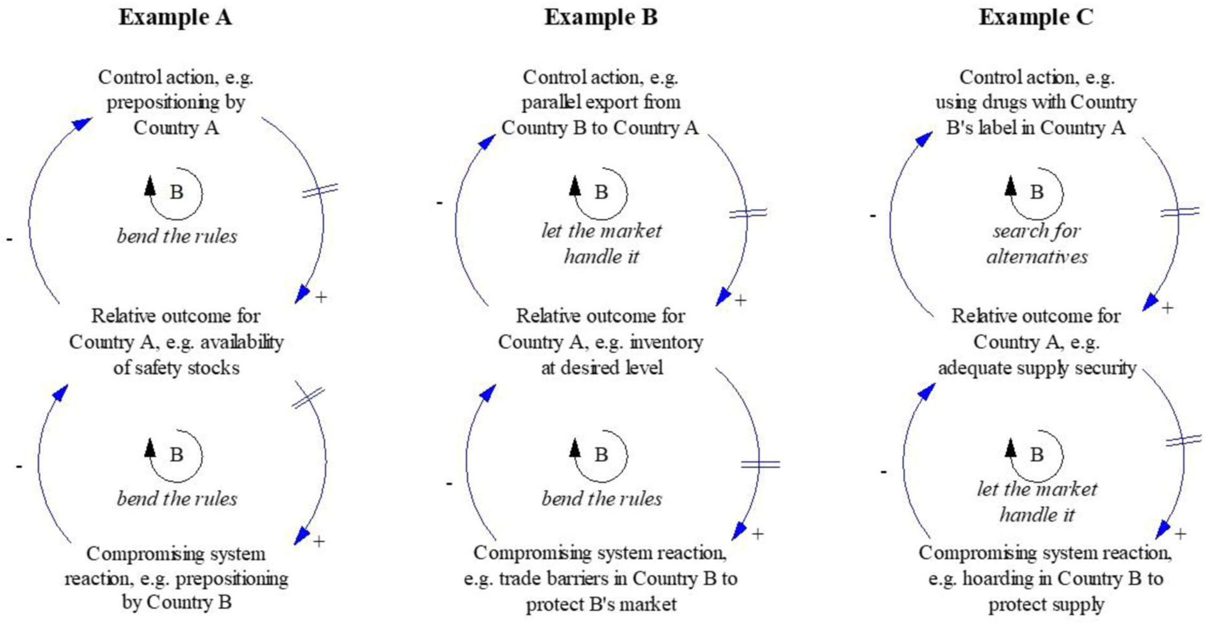

FIGURE 3 Examples of basic solution archetypes that activate compromising system reactions

Country B, as they face an increased risk of shortages. This, in turn, could negatively affect supplies to Country A. In this example, the "search for alternatives" archetype activates a "let the market handle it" archetype that compromises the effectiveness of using products with foreign labels. In the end, the problem for Country A is not solved, while Country B may end up with too much inventory.

These three examples show that in a compromising situation, two balancing loops counteract each other. Seen in isolation, they could potentially solve the problem, but in combination, they cancel each other out, at best. By focusing on one country only, it would be difficult to understand such compromising reactions in the bigger system. Furthermore, as it takes time for solutions to have an effect and to activate side effects (these delays are depicted in Figure 3 with two short parallel lines perpendicular to causal links), a snapshot of a drug shortage situation may not reveal these important phenomena.

4.4.2 | Examples of escalating system reactions

Besides activating a compromising response, basic solution archetypes can also trigger an escalating response, making the problem worse. In this situation, the basic solution, represented by a balancing loop, is overruled by its own side effect, which represents a reinforcing loop. This reinforcing loop aggravates the problem, which induces more of the same basic solution. In Figure 4, we show three examples in which a solution from one of the basic solution archetypes activates an escalating reaction.

Example D describes how industry actors can, under certain circumstances, voluntarily seek to increase transparency in their drug supply chain to increase preparedness for future shortages (following the "let the market handle it" archetype). But a side effect of such transparency could be that when shortages are foreseen or forewarned, industry actors (in different countries) could all start hoarding. This increases demand and causes a battle for drugs between producers. The result of such a response could be a demand for even more transparency (e.g., as actors losing the battle want to know where "their" drugs went) and even higher risks of hoarding.

Example E depicts how policymakers could tighten quality regulations to ensure supply security. These regulations are meant to reduce quality-related problems, which has a positive effect on supply security. However, more regulations could also increase production lead times. Longer lead times make supply chains more vulnerable to demand fluctuations, which decreases supply security.

Example F shows how finding an alternative for a drug that is lacking could backfire. Initially, it appears effective to offer patients an alternative, but when alternative drugs are used off-label (off-register), it could lead to a withdrawal of licenses, which reduces the number of manufacturers and worsens shortages in the long term.

These three examples show that a balancing loop can activate a reinforcing loop which makes the problem worse (in Figure 4, such a reinforcing loop is depicted with an R). Decision-makers who focus on a small piece of the puzzle within a short temporal and spatial horizon may not detect the escalating response.

4.5 | Toward higher-order solutions

By analyzing the feedback mechanisms of the higher-order system reactions, we derive higher-order solution archetypes that support decision-makers to find sustainable solutions

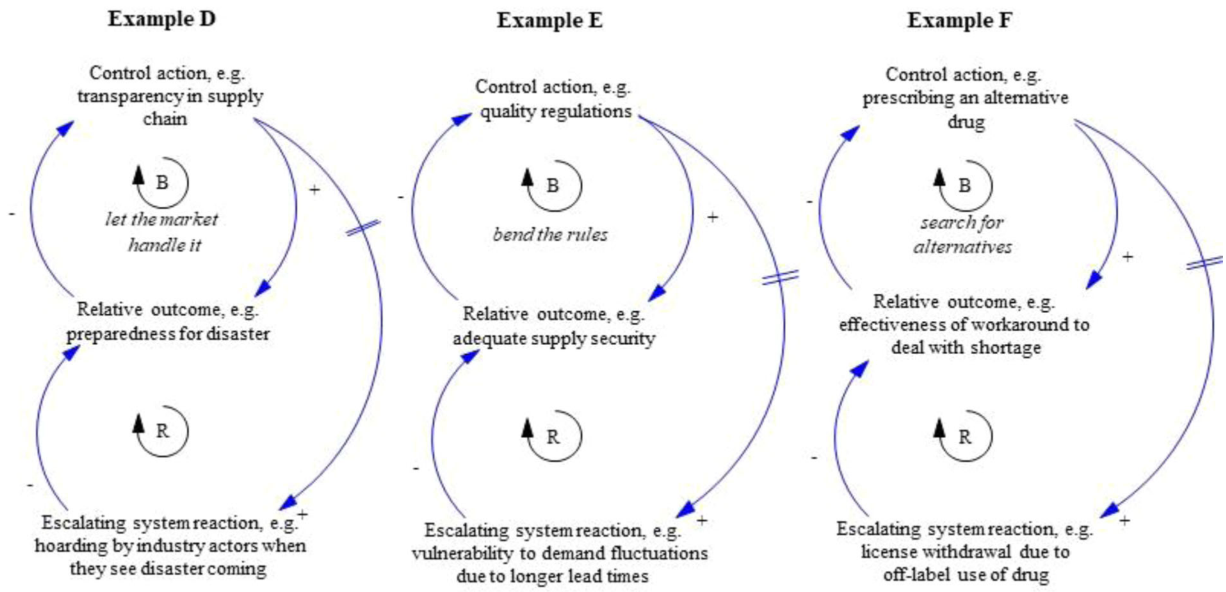

FIGURE 4 Examples of basic solution archetypes that activate escalating system reactions

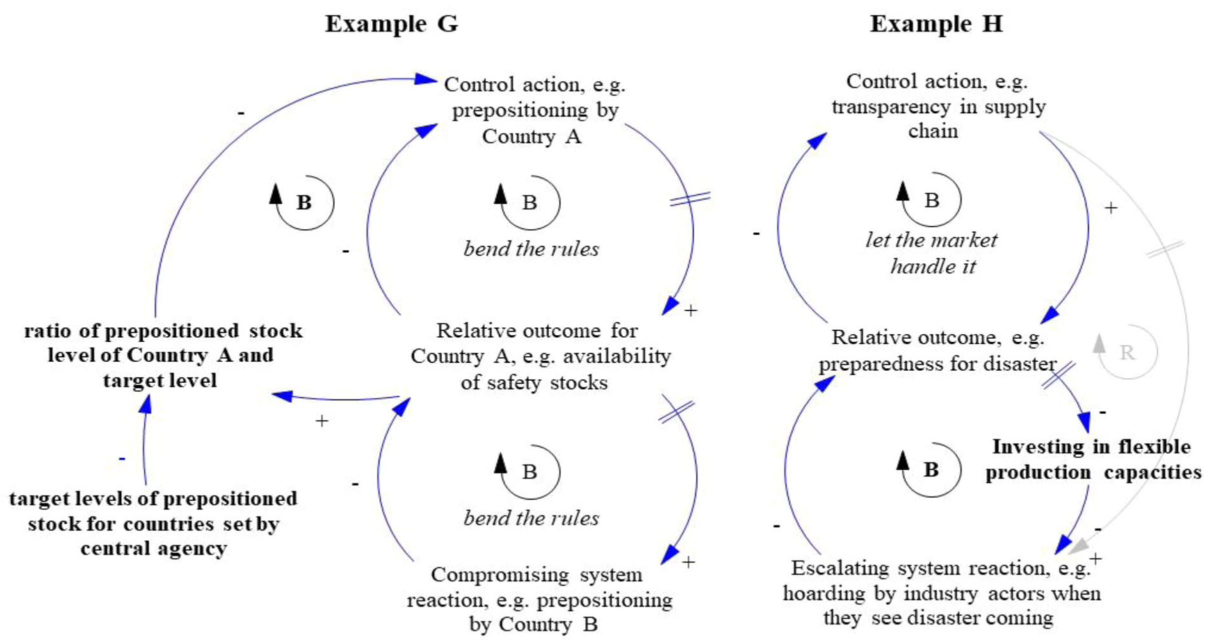

FIGURE 5 Examples of higher-order solution archetypes

(Wolstenholme, 2003). Figure 5 shows two examples of such higher-order solution archetypes.

Example G describes a higher-order solution to a compromising system reaction—an arms race between two countries. One way to stop the race is to install mechanisms that facilitate the centralized allocation of scarce inventories in line with countries' needs. This means introducing a third balancing loop that overrules or governs other balancing loops derived from the basic solution archetypes. The basic solutions remain intact, but the mode of governance changes: Centralized allocation through an independent third party or collaboration gives each country a fair share, and hoarding behavior is prevented.

Example H presents a higher-order solution to an escalating system reaction. An escalating response embodies a feedback mechanism consisting of a balancing loop with the intended solution and a negative side effect that activates a reinforcing loop, making the problem worse. A way to stop the reinforcing loop is to introduce a new solution that breaks the vicious circle of the reinforcing loop. For instance, instead of increasing transparency in supply chains to prepare industry actors for shortages, which could also lead to more hoarding, industry actors could invest in more flexible production capacities. This enables a faster disaster response and weakens the need for more transparency. In short, when a basic solution archetype leads to an escalating system reaction, one should search for a new solution (or a balancing loop).

5 | DISCUSSION

We submit that a systems view of the drug shortages problem requires a multicountry and multistakeholder analysis of interconnected cause-and-effect relationships. Our research thus provides a holistic systems view of drug shortages. We deliberately included public reports from a wide spectrum of stakeholders (policymakers, healthcare providers, and industry actors) who are separately focused on a wide array of generic drugs in multiple European countries, because we aim for inclusion. All identified cause-and-effect relationships matter, whether they are mentioned by only one country or by all six of them. All pieces of the puzzle enrich our understanding of the system and should be included. Decision-makers within supply chain entities, health providers, and agencies responsible for policy design and enactment should thus move beyond individual organizational and functional analyses toward a more systemic, holistic understanding (Craighead, Blackhurst, Rungtusanatham, & Handfield, 2007).

A systems view of drug shortages results from connecting linear cause-and-effect relationships. These interconnected relations in turn reveal certain archetype solutions to the problem. A systems view, therefore, entails that causes of shortages also represent solutions. Table 1 summarizes the main outputs of our research: basic solution archetypes to curb shortages in drug supply chains, their higher-order system reactions, and suggested higher-order solution archetypes. These outputs are linked to a set of research propositions which we discuss below.

The systems view of drug shortages consists of a very large set of interacting feedback loops, too complex for decision-makers to grasp and translate into action (refer to Appendix S7 for this elaborate system view). However, simplicity underlies the complex structure. Our analysis demonstrates a small number of solution archetypes common to a large variety of feedback loops. The first, "let the market handle it," refers to interventions by industry actors. The second, "search for alternatives," concerns interventions by healthcare providers and medical experts. The third, "bend the rules," refers to interventions by policymakers and regulatory bodies. Beyond the first two archetypes, which are well established in the literature (e.g., Pauwels et al., 2014), we show that temporary adjustments to regulations and policies can also help solve the problem. The mechanism underpinning each of the three basic solution archetypes is a balancing feedback loop. Each of these archetypes, seen in isolation, can resolve drug shortages. We, therefore, propose:

> **P1**: A systems view of drug shortages increases our understanding of solutions to the problem through three basic solution archetypes: let the market handle it; search for alternatives; and bend the rules.

Seen from a systems view, the identified basic solutions, too, form part of a bigger system and can have unintended side effects that eventually limit their effectiveness. Not all these side effects are easy to detect, either because it may take some time before they occur or because they occur in different places. Specifically, our analysis shows that the implementation of one basic solution archetype can activate another archetype. In other words, the basic solutions can trigger higher-order unintended reactions elsewhere in the system. Such higher-order system reactions are either compromising or escalating (Table 1). A compromising response entails a balancing side effect which counteracts the basic solution. As such, the intended effect of the basic solution is short-lived or local, and eventually, the problem persists. An escalating response, on the other hand, entails a reinforcing side effect which makes the problem worse. Unlike prior research that has stressed the positive effects of seeking complementarities between solutions—for example, combining price increases with contractual incentives and stockpiling (Jia & Zhao, 2017; Tucker et al., 2020)—we show that basic solutions, when they interact, generate unintended effects. In sum, we propose:

> **P2**: The basic solution archetypes interact and may generate "higher-order effects" which either compromise or escalate systemic reactions in drug supply chains.

> **P2a**: The drug shortage problem is complicated by compromising systemic reactions which attenuate the intended effects of basic solution archetypes by virtue of differences in the locus (single vs. multiple countries) and timing horizon (short vs. long term) of solution implementation.

> **P2b**: The drug shortage problem is complicated by escalating systemic reactions which reinforce the unintended negative effects of basic solution archetypes by virtue of differences in the locus (single vs. multiple countries) and timing horizon (short vs. long term) of solution implementation.

In addition to allowing us to identify compromising and escalating reactions to basic solutions, a system view of drug

TABLE 1 Basic and higher-order solution archetypes to curb drug shortages

Basic solution archetype (Proposition P1)	Characteristic	Result of the basic solution archetype	Feedback mechanism
Let the market handle it	Interventions by industry actors (as market participants)	Problem seems to be solved	Balancing
Search for alternatives	Interventions by healthcare providers/medical experts	Problem seems to be solved	Balancing
Bend the rules	Interventions by policymakers and regulators	Problem seems to be solved	Balancing
Higher-order effects of basic solution archetypes ((Propositions P2 (a–b))	**Characteristic**	**Result of higher-order effects of basic solution archetypes**	**Feedback mechanism**
Compromising system reaction	Solutions from different basic solution archetypes counteract each other	Problem persists (at best)	Balancing + Balancing
Escalating system reaction	Negative side effects of solutions from basic solution archetypes escalate the problem	Problem gets worse	Balancing + Reinforcing
Higher-order solution archetypes (Propositions P3, P4)	**Characteristic**	**Result of higher-order solution archetype**	**Feedback mechanism**
Preventing or overruling the compromising system reaction	Collaboration or centralization to avoid competition between actors	Problem is solved by a third balancing loop that governs the other two	Balancing + Balancing + Balancing
Preventing or overruling the escalating system reaction	Implementation of a fundamental solution that avoids local quick fixes	Problem is solved by a new balancing loop that removes the reinforcing loop	Balancing + Balancing

shortages helps to develop higher-order solutions to these types of reactions. Higher-order solutions to compromising system reactions essentially seek to prevent competition between supply chain actors by introducing a third balancing loop. This loop intends to invalidate or regulate the effects of the other two balancing loops counteracting each other. Such higher-order solutions are in line with approaches stressing centralization and collaboration in supply chains (e.g., Friday, Ryan, Sridharan, & Collins, 2018). In summary, we propose:

> **P3**: Compromising systemic reactions in drug supply chains can be counteracted through holistic solution archetypes that overrule neutralizing balancing loops and govern their effects through centralization or collaboration.

Our analysis also shows that introducing a new balancing loop can neutralize the effects of a reinforcing loop that is activated by a negative side effect of a basic solution. This type of higher-order solution emphasizes more fundamental solutions over interventions that can have positive effects in the short or medium term but also generate negative side effects. For example, although increased information sharing and transparency in the supply chain can help reduce drug shortages (Lee, Lee, Shin, & Krishnan, 2021), it can also trigger hoarding. Accordingly, we propose:

> **P4**: Escalating systemic reactions in drug supply chains can be counteracted through holistic solution archetypes that deactivate reinforcing loops through the prioritization of fundamental, longer-term solutions over short-term fixes.

5.1 | Implications and contributions

This article reports on the results of a wide-ranging fact-finding mission to analyze the current state of drug shortages as perceived and presented by practitioners and policymakers in their public reports. The value of this article is that it provides a comprehensive view of what practitioners and policymakers in different countries are doing to handle drug shortages, including an exploration of the pros and cons of such actions. Although the individual cause-and-effect relationships covered in the systems view are well known, putting together the disparate relationships from different countries and considering their interrelationships is what is offered by this research. Given the objective of the article, we chose to do a scoping review of gray literature (practitioner publications and public reports) from six European countries. Our scoping review aims to obtain broad coverage in identifying gaps in the perceptions of practitioners and policymakers. Consequently, we step outside the typical scientific methodology applied to a specific problem issue typical of most empirical research in our field. Instead, we position our work as a thought leadership article that uses a unique approach to develop knowledge on the drug shortage topic. This article is unique in terms of topic and research design and has the potential to shape the conversation and perhaps even the paradigms of researchers, as explained below.

Our study builds upon prior research on the causes and effects of drug shortages (e.g., De Weerdt, et al., 2015; Pauwels, et al., 2014), which tends to focus on a single country, stakeholder, or drug type (e.g., Heiskanen et al., 2017; Woodcock & Wosinka, 2013). We extend this literature by developing a systems view of the problem based on feedback loops. Our approach, consisting of a scoping review and systems dynamics modeling, allowed us to combine and connect linear cause–effect relationships. This holistic systems view required going beyond focusing on a single country, stakeholder, or drug. It enabled the development of research propositions regarding higher-order unintended effects of basic solutions and associated holistic solutions.

Our research contributes to literature stressing the positive effects of implementing a basket of solutions in a complementary fashion (e.g., Jia & Zhao, 2017; Tucker et al., 2020). We do so by showing that the basic solution archetypes interact with one another and generate higher-order unintended effects. Specifically, we demonstrate how the interrelation of basic solution archetypes can compromise intended behavior or escalate unintended behavior. Furthermore, our systems view allows us to identify specific ways of counteracting such unintended effects: higher-level solution archetypes that overrule such compromising or escalating behavior in the system.

Methodologically, we have demonstrated the usefulness of scoping reviews in an operations and supply chain context. Although this approach is well-established in health sciences, it is very rarely used in Operations Management (Tortorella et al., 2020) and seems to be nearly absent in Decision Sciences. Our method provides a feasible and inexpensive way to gather and analyze large sets of evidence on cause-and-effect relationships from multiple countries and stakeholders. We demonstrate how the results of a scoping review can be fed into systems dynamics models to build a comprehensive view of a problem.

Our research is grounded on a real-world problem, and we paid attention to how key stakeholders understand the problem. Thus, our findings have significant implications for decision-makers. First, we argue that there are no root causes of drug shortages in normal situations. Instead, a web of interconnected causal relationships underpins drug shortages, meaning that root causes are not merely difficult to find, but nonexistent. This is an important finding, especially considering efforts by supply chain actors and policymakers to find root causes of drug shortages, and a tendency toward quick fixes. Instead of focusing on "fishbone analyses" (i.e., linear cause-and-effect relationships) to find root causes, decision-makers should be focusing on "fishing net analyses," which allow them to connect linear relationships in a systems view of the problem. This would require close collaboration between key stakeholders. Although this view is less likely to offer decision-makers a single "right" answer, it will certainly yield an alternative, more useful framing of the problem.

Second, decision-makers can become more effective by adopting systems thinking and embracing complexity. Identifying linear cause-and-effect relationships per country is a good start, if one is aware that all mental models are inherently limited (Sterman, 2000) and that countries need to learn from each other. The basic solution archetypes and the system reactions they elicit, and the proposed higher-order solution archetypes, provide a way to deal with the complexity and causal ambiguity in the system. Such a systems view can be used to investigate how the structure and interactions between entities in the supply chain affect the propagation of delays, shortages, information, and technological innovation throughout the entire complex system (Basole & Bellamy, 2014). Furthermore, decision-makers should pay particular attention to the unintended side effects of basic solutions which exacerbate drug shortages. Interventions can unintentionally generate negative effects (Pournader, Kach & Talluri, 2020), and these need to be investigated and kept in check. A systems view can contribute significantly to this end.

5.2 | Future research directions

To create further knowledge about the cause-and-effect relationships of drug shortages, we see two ways of doing research. One way is the approach used in this article, where we focus on a systems view including multiple interrelationships to get a complete picture. However, the reality of academic research is that it often is only possible to study a few interrelationships at a time, using methods, such as stylized analytical modeling, simulation, or empirical analysis. Such formal testing of individual relations is the other way. Both should inform one another.

Our systems view of drug shortages opens exciting avenues for future research. Further research could build on our research propositions and turn them into testable hypotheses. Specifically, it is imperative to study further the types of unintended (negative) effects associated with basic solution archetypes, how and when these effects manifest themselves and propagate in supply chains over time, and what can be done to avoid them. Further empirical research is needed to understand better the mechanisms underpinning escalating and compromising systemic reactions, and to test and refine the higher-order solutions we have put forward. Given the ill-structured nature of problems decision-makers face and the time lag involved in identifying unintended reactions and corresponding solutions, a design science approach would be suitable to develop solutions with practical impact (Holmström, et al., 2009).

More broadly, our propositions regarding the basic and higher-order solution archetypes can be used as a baseline for further comparative research. First, future research extensions could focus on countries, drugs, or supply chain settings with different features. We studied six high-income countries with mature regulatory and legal frameworks to build our systems view of drug shortages. Further research could expand this approach to include countries with different characteristics (e.g., in terms of income level, regulatory environment, or governance system) to examine whether the archetypes are also present there or whether new archetypes must be added to the picture. Additionally, future research could compare the performance of different countries on the metric of shortages or on contingencies under which certain actions would be better. Second, our analysis focused on generic drugs. Further research is needed to analyze if and how the systems view changes when novel, patented drugs are considered. Third, we have studied drug shortages in normal times, thereby treating Brexit as an outlier and excluding cause-and-effect relationships related to this event. Nevertheless, such an exclusion should be treated with caution. Our systems view should not be biased by events that would have been included in the data given a different geographical and temporal scope of the data collection. Future research could test and possibly refine our results and propositions in settings of severe disruptions, such as natural disasters, the geopolitics of post-Brexit Britain, or other geopolitical tensions.

Future research should also focus more explicitly on the role of public policy and public agencies which design and enact policies and intervene in drug supply chains. An institutional economics perspective (North, 1990) would be particularly useful to this end. In addition to "bending rules," as and when required, to help resolve shortages, public agencies and regulatory bodies influence supply chains in a more fundamental way by creating the "rules of the game," that is, the institutional setup within which supply chain actors operate and interact with one another (Selviaridis & Spring, 2022). Government interventions can enhance or restrict the flow of resources between firms, thus magnifying the extreme shifts in supply and demand and altering power dynamics within supply chains, as power advantages shift upstream (Craighead, Ketchen, & Darby, 2020).

Research focusing on public policy is a topical theme in the context of government interventions seeking to promote resilience in supply chains (Scholten, Stevenson, & Donk, 2020) in response to the COVID-19 pandemic and geopolitical risks. The COVID-19 crisis also underlines the impact potential of our approach. The pandemic has tested the resilience of supply chains to an extreme degree. The reaction of decision-makers to COVID-19 provides examples of all basic solution archetypes and their compensating or escalating system reactions. Headlines in Forbes (July 2, 2020) and the BBC (March 4, 2020) provide an indication: "US Buys World Supply Of Remdesivir For Coronavirus" and "Coronavirus: Drug shortage fears as India limits exports." By bending the rules, nations can sometimes successfully curb shortages in the short term. However, this can trigger an escalating system response and result in aggravated shortages in the long term. The higher-level solution archetypes we developed in this research (Table 1) can support decision-making to sustainably reduce drug shortages in noncrisis situations and be better prepared for the next crisis. In light of the ongoing pandemic, we submit that developing such a holistic system approach is imperative.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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