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Value chain disruptions: policy responses to antibiotic shortages in global value chains

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Abstract
Significant disruptions have recently afflicted global value chains (GVCs), causing shortages of essential products like antibiotics. Antibiotic shortages are a prioritized issue for policymakers because they increase patient suffering and healthcare costs. Focusing on the case of Sweden, we use a unique dataset of generic antibiotic GVCs and show that more than three-quarters of them entail substantial shortage risk. Through extensive qualitative data, we first identify six policies currently under discussion by Swedish policymakers to address antibiotic shortages, and then discuss their potential impact on the configuration of antibiotics GVCs, as well as how these policies change when moving from the Swedish to the EU context. Our analysis shows specifically that mandatory parallel sourcing, relocations, and new reimbursement models are the three policies with the strongest expected effects. This study contributes to the GVC and international business literature by introducing three types of mechanisms (reinforcing, gathering, and multiplying) whereby policy can affect the resilience of GVCs. We also contribute novel insights about necessary changes in policies when moving from the national (Sweden) to the supranational (EU) level, as well as about how different types of GVC governance frame the relevance of policies for other small high-income countries.

Keywords GVCs · Disruptions · Resilience · Policies · Drug shortages · Antibiotics · International business

Introduction

The last few years have witnessed multiple disruptions to global value chains (GVCs) following the COVID-19 pandemic (Gereffi, 2020; Gereffi et al., 2022), the war in Ukraine (Mariotti, 2022), rising economic nationalism (Luo, 2024), and the rivalry between the United States and China (Tung et al., 2023; Witt et al., 2023). In response, governments and supranational bodies, like the European Union (EU), have devised or introduced policies to make essential GVCs more resilient (Gereffi et al., 2022), meaning able to plan, absorb, sustain, and adapt to external shocks and disruptions (Pettit et al., 2010).

Research in various fields, including international business (e.g., Gereffi et al., 2021), economic geography (e.g., Smith et al., 2014), and supply chain management (e.g., Sodhi et al., 2023), has recognized how policies can mitigate or help recover from disruptions in GVCs (Dadush, 2023; Miroudot, 2020). For instance, Fu et al (2022) suggest that, for vaccine production in case of pandemics, governments and international organizations (e.g., the World Health Organization) should support the development of international joint ventures with pharmaceutical manufacturers in industrialized and emerging countries. However, there is little consensus, and a *first research gap* concerns the goals and impact of these policies. Some argue that resilience can be improved through shorter, more regionally concentrated GVCs (Kamakura, 2022; Pedroletti & Ciabuschi, 2023), while others advocate for more globalized and diversified

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ones (e.g., Jiang et al., 2022; Miroudot, 2020). This divergence may depend on different research assumptions, different types of policies examined and of disruptions addressed. Moreover, studies of GVC disruptions and resilience have mostly focused on firm-level strategies, i.e., how firms can cope with disruptions and/or policies. To address this *second gap*, this paper focuses on the policies themselves, i.e., their content and effects on firms and value chains (e.g., Choksy et al., 2022).

This paper centers on GVCs for essential products, namely antibiotics – a drug class with immense social value, saving millions of lives yearly from infections and making other therapies such as surgery or chemotherapy possible at all. But the COVID-19 pandemic made even more clear the risks and weaknesses of antibiotics GVCs, exacerbating the problem of shortages (Technopolis Group, 2021), defined as instances "when the market authorization holder (MAH) is unable to meet the demand for a product on a national level" (Swedish Medical Product Agency, www.lakemedelsverket.se[1]). In Europe, antibiotics are among the medicines most often subject to shortages (Technopolis Group, 2021), and the lack of antibiotics causes unnecessary patient suffering, additional work to hospital staff and considerable costs to healthcare and society as a whole (Phuong et al., 2019), while also accelerating the major global challenge of antibiotic resistance. Given the criticality and urgency of antibiotic shortages, policymakers, both nationally and at the EU level, started considering policy interventions (see e.g., Anderson et al., 2023; TLV, with LV & Fohm, 2022; WGEMA, 2022).

While previous studies on policies and GVC resilience mainly focus on the firm and the country levels (Miroudot, 2020), this paper considers also a third level of analysis, namely product categories such as antibiotics and even specific products such as Penicillin V. This level of analysis is necessary because each single product is not easily interchangeable in therapeutic applications and, as we shall see in the sections "Conceptual framing" and "Causes of shortages and the antibiotics GVCs in Sweden", GVCs are highly fragmented in terms of production phases, with links that are difficult to substitute due to technical and regulatory constraints (Baraldi et al., 2023).

Our study focuses on the case of Sweden because this country has an historically strong position in the pharmaceutical industry (with major companies like Pharmacia, then acquired by Pfizer, and Astra, then merged into AstraZeneca) and still growing drug exports (from €5 to €12 billion between 2012 and 2022); however, its role in antibiotics GVCs has declined in the last decades, with only one Swedish factory left producing a restricted number of antibiotics.[2] With a small population of around 10.5 million and very low antibiotic use (less than 300 prescriptions per 1000 inhabitants/yearly), Sweden's market is hardly prioritized by large suppliers, raising the risk of antibiotic shortages (Baraldi et al., 2023). In fact, the Swedish Medical Product Agency (SMPA) recorded 337 antibiotic shortages in 2018–2024. These challenges, shared by other small high-income countries, led Sweden to pioneer policies against antibiotic shortages.

There is a wide range of policies under discussion both in Sweden and in the EU: for instance, new payment models aimed at improving the availability of specific medicines and public support to bring back to Europe value chains previously offshored (Directorate General, 2021). However, no policy against antibiotic shortages has yet been implemented, even if discussions have been ongoing since 2020, both at the national and EU levels, which makes this study very timely for policymakers. These two levels of analysis must be considered because while healthcare is a competency of member states, the EU owns a shared competency on public health safety concerns. In this regard, it is worth noting that GVC scholars generally recognize that "countries and regions tailor their GVC-related objectives, rationales, and instruments to their socio-economic context" (Pietrobelli et al., 2021, p. 8). Moreover, Moore et al. (2024) suggest that national governments should carefully evaluate the relationship between the supranational and national level. Therefore, it is important to consider the actual context of policies because adaptations may be necessary when moving between the national level (e.g., Sweden) and the supranational one (EU), an issue so far unstudied, which is accordingly the *third gap* we address in this paper.

Against this background, this paper takes a problem-centric perspective in order to provide "policy insights" – i.e., "a deeper understanding of the context and underlying factors that surround a public policy challenge" (De Marchi et al., 2025, p. 6) – about the problem of antibiotic shortages. More specifically, we aim to identify and analyze *the potential impact of public policies, which are currently under development against antibiotic shortages, on GVCs'*

[1] Definitions of drug shortages may slightly vary between countries. This paper follows the Swedish definition, which is also aligned with the EU's, as our study centers on Swedish policies against antibiotic shortages.

[2] Even if about ten Swedish companies are registered with the Swedish Medical Product Agency as manufacturers of "final dosage formulations" (FDF), most of these actors deal only with re-packaging, and only one factory actually produces antibiotics in Sweden starting from active pharmaceutical ingredients (API). These APIs for antibiotics, however, need to be imported from abroad because Sweden's last antibiotics API factory closed in 2001 after 50 years of operations (Baraldi et al., 2023).

configuration. To achieve our aim, we address the following research questions:

1. What are the main policies currently discussed to tackle antibiotic shortages?
2. How can these policies affect the geographic and organizational configurations of antibiotic GVCs?
3. How do these policies and their effect change if we consider the national (Sweden) as opposed to the supranational level (e.g., EU)?

Our study contributes to three literature streams: international business, GVCs, and international business policy. To the first two streams, we contribute an analysis of the potential effects of policy on the resilience of GVCs by specifically targeting their geographic and organizational configuration. In particular, our findings show that policies addressing one and the same problem (antibiotic shortages in our case) can both increase geographic proximity (Kamakura, 2022; Pedroletti & Ciabuschi, 2023) and make GVCs more global and diversified (e.g., Jiang et al., 2022; Miroudot, 2020). We also contribute to the GVC literature by taking a policy, rather than a firm's perspective, which allows us to identify three distinct mechanisms that policymakers can use to improve resilience, namely reinforcing a single chain, bringing it geographically closer, and creating multiple and geographically diversified GVCs. To the third literature stream, international business policy, we provide new insights not only on the effects of national policies on global GVCs but also on the adaptations of policies from the national to the supranational level.

This is the first study focusing on GVCs for antibiotics, a specific problem related to their disruption, that of antibiotic shortages, and a set of specific policies currently still debated. Therefore, it is anchored to a current policy issue that is attracting the attention of various policymakers (De Marchi et al., 2025). In this respect, an *ex-ante* evaluation of the potential effects of policies under discussion is equally, if not even more relevant for policymakers than analyzing *ex-post* the effects of already implemented policies. Moreover, this paper is particularly relevant for policymakers of small high-income countries which, similarly to Sweden, are more exposed to high dependence on global GVCs (Crowe & Rawdanowicz, 2023; Lanz & Werner, 2018) for essential drugs.

The remainder of the paper first explains our analytical framing and its key components. After a method section presenting our data sources and analysis, we describe the specific features of Swedish antibiotics GVCs and six selected policies aimed to address antibiotic shortages. We then analyze the potential impact of the six policies on the organizational and geographic configuration of GVCs. We end the paper by presenting our research contributions and the relevance of our study for policymakers.

Conceptual framing

Recent disruptions had a significant impact on GVCs and their configuration, an impact visible in our case as antibiotic shortages (see area A in Fig. 1). Public policies aim at preventing and/or reducing shortages (see the double arrow in Fig. 1), but while doing so, policies also affect the configuration of GVCs (area B in Fig. 1). Our study focuses on this latter relation, i.e., *public policies*' impact on *GVCs configurations* (Gereffi et al., 2021), the two key elements that we now discuss further.

Global value chain configurations and resilience

About 50% of global trade occurs through GVCs, making them "the world economy's backbone and central nervous system" (Cattaneo et al., 2010, p. 7). The GVC concept emerged as an evolution of the global commodities chain developed in the 1990s. It describes the interconnections between the notion of value-added chains and the organization of industries at the global level (Gereffi & Korzeniewicz, 1994). Several scholars investigated value creation through all kinds of chain activities (e.g., De Marchi et al., 2020; Gereffi & Lee, 2012; Kano et al., 2020). GVCs are conceptualized as both a phenomenon characterizing several industries (Staritz et al., 2011) and as a framework to investigate the global organization of industries and its impacts on firms' strategies and local development (Gereffi, 2014). In this respect, the GVC approach offers an "outside-in" perspective on multinational companies that analyzes their relationships with the other actors within the network (McWilliam et al., 2020). The main actor within a GVC is the lead firm (usually, a multinational company), which may be a manufacturer (in a "producer-driven chain") or a retailer (in a "buyer-driven chain") (Gereffi, 2018; Gereffi & Korzeniewicz, 1994). Such an actor orchestrates the contributions of several organizations operating in more than one country, which may be either independent firms or belonging to the lead firm's "enterprise group" (European Council , 1993).

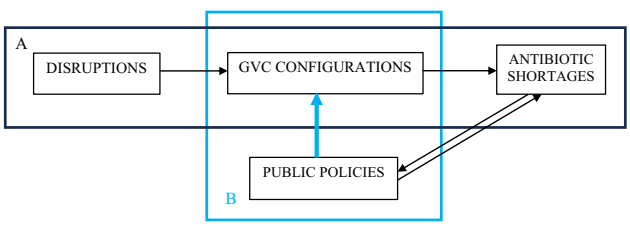

Fig. 1 Links between public policies and the configuration of GVCs

The configuration of GVCs entails a *geographic* and an *organizational* dimension (Gereffi et al., 2021). Both dimensions affect GVCs' resilience, that is, their ability to adapt to disruptions (Pettit et al., 2010). More specifically, the geographic dimension regards the distribution of the different value chain activities around the globe, with the lead firm either concentrating or dispersing them (Kalchschmidt et al., 2020). A general trend has been moving from localized value chains to de-integrated and highly geographically widespread chains, which were able to achieve efficiency gains, such as cost reductions by exploiting the comparative advantages of specific locations (e.g., access to raw materials or inexpensive workforce). However, these long, complex, and geographically spread value chains also bring disadvantages, especially in terms of supply risk and resilience (e.g., Gereffi et al., 2022), which become evident with shortages. Strong geographic concentration of all players in a specific link of GVCs (e.g., raw material suppliers or assemblers) can also create strong dependence and hence increase supply risk (Baldwin & Evenett, 2020).

The organizational dimension of GVCs regards "linkage heterogeneity" (Kano et al., 2020) of both vertical and horizontal links. Vertical heterogeneity concerns the degree of integration/fragmentation of value chain activities, ranging between complete vertical integration in the same company and total fragmentation involving one or several independent suppliers in the various links. Horizontal heterogeneity concerns instead the number of actors, such as alternative suppliers, involved in each step of a GVC. The two heterogeneity dimensions in turn characterize relationships within a GVC in terms, e.g., of power relations and degree of coordination (ibid, p. 584). Vertical integration and low horizontal heterogeneity favor transparency, making GVCs easier to overview.

Geographic and organizational configurations influence how vulnerable GVCs are to disruptions. More specifically, both alternatives of geographic dispersion and concentration can affect resilience negatively because dispersion entails longer delivery times and reduced reactivity, while concentration increases risk exposure due to the co-location of all the activities of a GVC. Therefore, a balance between these alternatives is necessary. At the same time, organizational fragmentation impacts resilience negatively due to high coordination efforts requested for the lead company to orchestrate several suppliers during a disruption; while vertical integration and low horizontal heterogeneity (i.e., a single supplier in each chain link) boost the effects of disruptions by preventing shared risk across several suppliers. Therefore, to improve the resilience of a GVC, the lead firm has to manage a double trade-off related both to geographic concentration/dispersion and to organizational integration/fragmentation. Finally, the effects of disruptions may also vary depending on other characteristics of GVCs. For instance, the GVCs of generic drugs suffer from depressed profit margins, which hinder maintenance and upgrading of production plants, thereby increasing risk of stops and accidents, and chain actors' limited competence in forecasting highly fluctuating demand or even managing flows across the chain (Huq et al., 2016).

As disruptions are becoming more frequent, improving GVCs' resilience has increasingly attracted the attention of scholars, especially after the COVID-19 pandemic (Klarin et al., 2024). Authors generally reckon that "the underlying principles of GVC governance remain unchanged" (Kano & Oh, 2020, p. 1776). Therefore, they do not consider deglobalization (including relocating production activities in the home country or region) a viable long-term alternative (Dadush, 2023; Gereffi, 2020). Instead, companies need to implement risk mitigation approaches (Lorenzen et al., 2020), for instance, involving more suppliers in more countries (Gereffi, 2020; Strange, 2020). Not only firms but also countries need to be more resilient, meaning able to rapidly return to deliver societal well-being after disruptions (Miroudot, 2020). Therefore, a more holistic approach is warranted, which carefully considers the interplay between firms and states, especially for essential GVCs like those of healthcare products (Gereffi et al., 2022).



Fig. 2 Typical value chain for antibiotics (Source: Baraldi et al., 2023, p. 625)

The weaknesses of antibiotic GVCs: Resilience and shortages

A typical antibiotic GVC (shown in Fig. 2) includes five steps: (1) API producer (Active Pharmaceutical Ingredient: the main raw materials to produce drugs) – (2) FDF producer (Final Dosage Formulation), who receives API and excipients to produce the final-formulation drug (e.g., pills, drinkable mixtures, injectables) – (3) MAH (Market Authorization Holder), that is, the actor selling the final product in a given country – (4) wholesaler (holding local inventories) – (5) hospital for in-care use or pharmacy for out-care use.

The roles of MAH, API producer, and FDF producer are generally performed by different companies which may either belong to a vertically integrated business group or be independent. MAHs can be generally considered as the lead firms (Gereffi, 2018) of antibiotic GVCs because they are the only actors allowed to perform sales in the countries for which they hold market authorizations, either by using their own vertically integrated FDF factories or by outsourcing production to contract manufacturers who own FDF factories. For generic antibiotics GVCs, governance structures can belong specifically to two of the strands proposed by Haakonsson (2009) for pharmaceutical GVCs: namely "quality generics", led by powerful MAHs acting as buyers, and "low-value generics", which are not driven by any lead firm, but have smaller MAHs who integrate supplies from an open market (ibid, pp. 85–87). As we will see in the section "Causes of shortages and the antibiotics GVCs in Sweden", these are the two types of antibiotics GVCs that supply Sweden.

Antibiotics GVCs are typically vertically de-integrated and, following multiple waves of offshoring since the 1990s, they are geographically concentrated with Chinese firms highly specialized in API and Indian firms in FDF production (Cogan et al., 2018; FDA, 2019). MAHs can be either local actors operating in single national markets or multinational companies with large market and product portfolios. This geographic concentration of specific production links in single offshore countries represents a general weakness of antibiotics GVCs because of geopolitical risk (Baldwin & Evenett, 2020; Miroudot, 2020). But the resilience of specific GVCs is jeopardized also by a more specific weakness, namely overdependence on very few suppliers (Costantino & Pellegrino, 2010), with the whole world's needs for specific antibiotics depending often on one or two factories only, sometimes located in areas with limited security controls and higher risk of accidents: for instance, a global shortage in 2017 of the key antibiotic piperacillin-tazobactam was caused by a fire in the only factory in the world producing this API, located in China (Shafiq et al., 2021).

As the vast majority of antibiotics sold are generics (Finch, 2010), i.e., products without patent protection, another weakness of antibiotics GVCs concerns the low profit margins available to sustain and increase the resilience of these chains (Huq et al., 2016). In particular, this involves end-customers' purchasing procedures, with tenders focusing on cutting prices, which continuously squeeze margins for all players in antibiotics GVCs and thereby reduce resources to upgrade and maintain facilities, making them more prone to risk of accidents and malfunctioning (FDA, 2019). This cause of shortages is compounded by notorious difficulties in moving production to new factories due to regulatory obstacles in transferring permits. Moreover, the antibiotic production system is rigid, as it requires very large batches (often larger than a country's yearly demand) and long lead times (Baraldi et al., 2023). This technical rigidity creates a further weakness in antibiotics GVCs because it hinders matching supply and needs whenever even minimal demand fluctuations or supply disruptions occur. The resilience of these value chains is further reduced by very low levels of inventories, which are considered as an excessive cost by all GVC actors. However, Just-in-Time cannot be applied in antibiotic GVCs due to large geographic distances between their links, weak relationships and limited coordination between their various actors, and insufficient demand forecast ability and supply management (Huq et al., 2016).

Summing up, antibiotics GVCs present several weaknesses that jeopardize their resilience and make them prone to shortages: geographic concentration in offshored locations, overdependence on single factories in key links, very low profit margins, inflexible production systems due to technical rigidities, lack of slack such as sufficient inventories, and limited coordination among chain links. These weaknesses make antibiotics GVCs less resilient and unable to face an unpredictable demand, as happened during the COVID-19 crisis. Finally, there is the extreme case of MAHs, which may withdraw from the market products that have been unprofitable for several years, causing a whole product-specific GVC or some of its links to disappear permanently. In the the section "Causes of shortages and the antibiotics GVCs in Sweden" we will present further details on the specific causes of antibiotic shortages afflicting Sweden, but the weaknesses of GVCs already highlighted in this section are serious enough to motivate policy actions.

Policies targeting shortages in GVCs

According to the OECD, industrial policies can be defined as interventions by government and other public bodies aiming to improve the business environment or economic structure for better growth or social welfare (Warwick, 2013). Policies can focus on specific sectors, in our case, the antibiotics field. Concerns about national security may trigger policies

aiming to change global industries, especially in strategic sectors like pharmaceuticals. However, devising such new policies is challenging because they have to simultaneously address several potentially conflicting goals, such as economic competitiveness, national security, sustainable economic growth, and social upgrading (De Marchi & Alford, 2022; Horner & Alford, 2019; Morris & Staritz, 2019). Moreover, policies could deliver both upgrading as well as downgrading effects on GVCs (De Marchi et al., 2022), especially if they are driven by governments' overreaction when facing disruptions, resulting in unintended and counterproductive effects in the name of national security and urgency (Dadush, 2023).

Policies vary in terms of economic interventionism (Ikeda, 1997), including (1) regulations (e.g., permits and prohibitions) and incentives (e.g., subsidies and tax breaks), which apply equally to all players in an industry; (2) direct interactions between public bodies and specific counterparts (e.g., public procurement and public–private partnerships); and (3) explicit takeover of economic activities by public actors (e.g., public services and acquisitions of corporations by authorities). Thus, different policies can make public bodies interact with private actors in various ways: taking over economic activities, long-term partnering, arm's-length relations, incentivizing, and regulating (Ikeda, 1997).

Looking in particular at the role the state can play in GVCs, Horner (2017) and Horner and Alford (2019) identify four general roles: (a) *facilitator,* by removing market-related obstacles in areas like trade and innovation; (b) *regulator*, by setting rules which reduce negative market externalities and unequal value distribution; (c) *producer,* via state-owned production activities; and (d) *buyer*, by procuring products and services according to specific requirements and economic conditions. A single state can also change roles in an attempt to affect one and the same industry, as witnessed by South Africa (Horner, 2022). This country, similar to Sweden, is largely dependent on drug importation and initially sought to promote national pharmaceutical production by adopting a facilitator role. However, it later had to assume the role of producer through the establishment of a state-owned API plant, and ultimately shifted to the role of buyer through centralized public procurement of medicines (ibid). While these types of policies are particularly relevant for countries lacking national production of strategic products like medicines, they can also be relevant in increasing the resilience of GVCs for these very products.

In particular, Pietrobelli et al. (2021, pp. 338–339) stress that policies addressing GVC resilience should strive to create a sufficiently diversified supply base, with limited dependence on GVC links in countries with high trade-related risk or production disruptions. This logic of risk diversification points out the limits for resilience of a GVC geographically concentrated in a single country, even if this is the home country of policymakers (ibid; Miroudot, 2020). However, despite this conceptual critique, several countries are considering policies to support reshoring one or several GVC links (e.g., Elia et al., 2021; Horner, 2022; Pegoraro et al., 2022), probably because if one considers a single GVC, a proximately located GVC is *ceteris paribus* more reliable thanks to easier monitoring and control (including regulations) than one located far away (e.g., Pegoraro et al., 2022).

Further, the governance structure of the targeted GVCs can make policies more or less effective for resilience. In particular, as previously mentioned, antibiotics GVCs can either be led by powerful MAHs selling "quality generics" or lack any lead firm because small MAHs buy production capacity from an open market for "low-value generics" (see Haakonsson, 2009, pp. 85–87). When reacting to policies where the state takes the buyer role, powerful MAHs in the former governance type can exploit their strong bargaining power more than smaller MAHs in the latter governance type. Similarly, policies whereby the state acts as a facilitator offer advantages that powerful lead firms can exploit more easily than GVCs lacking lead firms. Instead, regulator-based policies are likely to apply similarly in GVCs with both types of governance.

Looking into specific policies, Pietrobelli et al. (2021, pp. 338–339) consider multiple GVC resilience policies, such as buffer stocks, rapid access to supply alternatives, including subsidizing local production of essential goods, and the creation of public–private partnerships focusing on both social and private values in a GVC (Findlay & Hoekman, 2021, p. 398). While there are several studies on the inner functioning of public–private partnerships (e.g., Bryson et al., 2006) or of the macroeconomic effects of regulations and subsidies (e.g., Michaillat, 2014), there is limited knowledge on how these policy interventions specifically affect GVCs in terms of configuration and relationships among their actors. For instance, we lack knowledge about policies' effects on relocations of GVC activities (Barbieri et al., 2019; Gereffi et al., 2021), especially on processes of reshoring to the home country (backshoring) or a nearby country (nearshoring). Academics (Enderwick & Buckley, 2020; Verbeke, 2020), international institutions and practitioners view reshoring as a potential reaction to major crises like COVID-19 (Elia et al., 2021; Pegoraro et al., 2022; UNCTAD, 2020; Zhan, 2021). However, policies alone may not be enough to drive relocations because highly structured GVCs may show resistance to change (Kamakura, 2022). Moreover, the nature of the specific policy target, such as shortages of essential goods (Colon & Hochrainer-Stigler, 2023) or geopolitical concerns (Gao et al., 2023), may frame a policy's influence on relocations. Policy effects may also vary considerably depending on whether policies are an antecedent of

relocation or if they are introduced along ongoing relocation processes (Pedroletti & Ciabuschi, 2023).

Finally, considering our third research question, based on the government body behind the policies and their geographic reach (e.g., Dar et al., 2016; Fromhold-Eisebith, 2007; Kakderi & Tasopoulou, 2017), policies can also be classified into *national* (e.g., Sweden or France), contiguous *regional* (e.g., Scandinavia), or broadly *regional* (e.g., the EU).

Method

Our analysis relies on an exploratory case study (Eisenhardt, 1989; Meredith, 1998) grounded in Sweden, which offers a relevant context to investigate both antibiotic shortages and related policies for several reasons. In particular, Sweden is increasingly afflicted by shortages because it virtually lacks home production of antibiotics (only one FDF producer is left) and is very exposed to GVCs for antibiotic supply, which results in Sweden being deprioritized by international suppliers because it is a small country. However, at the same time, Sweden seeks a wide variety of antibiotic products, all in small volumes, to be able to rotate antibiotics in use and hence contain antibiotic resistance. As for policies against shortages, Sweden is a forerunner. Following intensive work since 2017, Sweden was the first country ever to introduce in 2020 a revenue guarantee model for newer exclusive antibiotics and to establish a multi-sectoral platform (PLATINEA, see below) to discuss policies against shortages of older antibiotics. Further, Sweden is currently discussing several other policies to improve access, i.e., reduce shortages for generic antibiotics, which are the focus of this paper. The international relevance of the Swedish case also derives from the fact that the recent Swedish Presidency of the Council of the European Union (2023) proposed explicitly to introduce a set of similar policies at the EU level.

In constructing our study of how policies proposed to address antibiotic shortages affect GVCs, we rely on (1) data about the GVCs of all generic antibiotics sold in Sweden and (2) data about the policies proposed in the Swedish and European context. To explore the policies' potential effects on GVCs, we interpreted (Alvesson & Kärreman, 2007; Denzin, 1994) a third source of empirical materials in the form of expert opinions of Swedish and international stakeholders representing various links of GVCs and reports by the multisectoral collaboration platform PLATINEA[3]. The reports feature single policy options and their expected impact in terms of reducing antibiotic shortages. More details are provided below about our data sources as well as our data analysis and interpretations.

Data sources

We collected both primary data (a structured database about antibiotics GVCs, semi-structured interviews, informal conversations, workshops/focus groups, participant observations, email correspondence, and steering group meetings minutes) and secondary data (policy reports). These data sources covered the three key elements in our research questions: the nature of GVCs, policies against shortages, and their potential effects. More details are provided below:

(1) *GVCs:* In this study, we make use of a unique set of primary data comprising all GVCs for all antibiotics registered and available in Sweden. This quantitative dataset was provided to our research team in 2020 by the Swedish Medical Products Agency (SMPA), and it includes for each antibiotic the following dimensions: (1) substance (active pharmaceutical ingredient, API); (2) type of formulation (e.g., capsule or vial) and strength (e.g., 200 mg or 1 g); (3) identity and nationality of the MAH; (4) number, identify and geographic location of factories performing final dosage formulation (FDF); and (5) number, identity and geographic location of factories producing the API. More specifically, the geographic location of MAHs concerns the company, whereas for FDFs and APIs locations it refers to a specific plant; hence, each FDF and API entity entails a single factory.

(2) *Policies:* Our data concerning policies includes secondary data from policy reports (see the subsection on data analysis for details) and especially multiple sources of primary data (Morse, 2009) collected between 2014 and 2024. The primary sources of empirical material include direct and active participation (Levin & Greenwood, 2001; Yin, 2003) in more than ten policy-related projects (half of which concerned policies against antibiotic shortages in a European and especially Swedish context), interviews, and workshops/focus groups (Miles & Huberman, 1994). Specifically, we conducted over 40 formal interviews (see Table A in Appendix for an overview) and had more than 100 informal conversations with many representatives of key stakeholders in the antibiotics field – for instance, producers at various links of GVCs, MAHs for several antibiotics in the Swedish and European markets, logistics partners, healthcare providers (especially infectious disease doctors) from over 10 hospitals in Sweden, drug purchasers and pharmacy managers, policymakers at several

[3] PLATINEA aims to stimulate innovations for existing antibiotics. This Swedish collaboration platform includes 22 partners representing companies, public authorities, academia, and healthcare. One of PLATINEA's main goals is to improve access to antibiotics in Sweden by suggesting policies to reduce antibiotic shortages (www.platinea.se).

Swedish and European health authorities (e.g., the SMPA, the Public Health Agency of Sweden, PHAS, the European Medical Product Agency, EMA, and the Health Emergency Preparedness and Response Authority, HERA), and health technology assessors and reimbursement experts. Field notes were written for most of these conversations and interviews, 20% of which were also recorded.

(3) *Expected effects:* In the period 2017–2024, one of the paper's authors has been directly involved in organizing about 70 interactive workshops and focus groups, on a monthly basis, with the aforementioned stakeholders to focus specifically on antibiotic shortages and possible policy solutions in the Swedish context. The role of this person was to coordinate the meetings by setting the agenda (together with another coordinator not involved in this paper), facilitating discussions between participants and organizing voting procedures when various stakeholders expressed their preferences on selected policies. Records for most of these workshops were collected in the form of meetings' minutes of Work-Packages 1 and 4 of the collaboration platform PLATINEA. We also gathered about 50 steering group meeting minutes of the same platform. Moreover, we have had access to thousands of e-mails exchanged between the above stakeholders within the PLATINEA platform in the period 2017–2024 (about 1500 e-mails per year over 7 years). One of the authors has been constantly involved in these e-mail conversations and has knowledge of their content concerning issues such as prioritized products in terms of public health or products with higher supply risk, how to handle upcoming shortages, identification of alternative providers, new payment models to avoid deregistration, etc. Overall, these primary data from interviews, conversations, focus groups, and e-mails cover the various stakeholders' views of the causes of antibiotic shortages as well as preferred policy options and their expected effects. These views are based on the roles and positions of the various actors within antibiotic GVCs, distinguishing between API producers, contract manufacturers of finished drugs, MAHs, and logistic partners and purchasers, also including the differences between larger and smaller providers (see Table A in Appendix for the variety of organizations involved).

Data analysis

As for the database of Swedish *antibiotics GVCs*, we first cleaned it from deregistered or exclusive (i.e., non-generic) final products. This resulted in a total of 367 GVCs, each one including one MAH, and at least one FDF factory, and one API factory. Second, we organized available data in a structured way to characterize GVCs in terms of their geography (based on the location of MAH companies and FDF and API factories) and organizational configuration (measured in terms of the number of factories involved at the API and FDF stages). Based on such analysis, we identified different types and levels of supply risk (see the section entitled "Causes of shortages and the antibiotics GVCs in Sweden").

The data collection, selection, and characterization of *policies* against shortages, addressing our first research question, applied the following procedure. As our third research question focuses on the linkages between the national and regional (European) levels, we started by orienting our search towards policies that had been discussed both by Sweden and by the EU. As already mentioned, Sweden is a particularly interesting context of study because of recurrent shortages (related to its particular needs and dependence on foreign suppliers) and its highly proactive approach as a first-mover in developing new policy interventions against shortages. In particular, we identified our initial "population" of policies in a document prepared for the Swedish government and the PHAS for possible collaboration among the Nordic countries to improve antibiotic availability. This document features 30 policies also discussed in various reports at the European level: Anderson et al.(2023) for the European Health Observatory (EHO), Swedish Presidency of the Council of the European Union (2023), European Commission, European Health and Digital Executive Agency (2022), TLV (2022), WGEMA (2022), Technopolis Group (2021), and PLATINEA (2020a). As a first step in the analysis of these policies, we merged those that had common features (e.g., three policy options aiming to improve transparency) and separated some policy elements that deserved to be treated as separate policies for our research purpose (e.g., "parallel sourcing" within the broader policy of "good purchasing practices").

We then analyzed the remaining policies to select those most relevant for our research aim, on the basis of the following criteria: (1) wide support in many reports; (2) good chances of being implemented in the near future in Sweden and EU; and (3) a clear theoretically relevant impact on GVCs. Thus, we immediately excluded policies that lack a theoretical connection to GVCs (e.g., "new frames to evaluate the value of antibiotics" or "priority lists") or that require collaboration between two countries (e.g., "mutual recognition of approvals"). These three criteria helped us single out nine policies. We then applied a final criterion for our selection of *six policies* (shown in Table 6 in the section "Swedish policies against antibiotic shortages and their impact on GVCs"): each policy should entail at least one more role of the state than traditional buyer of drugs, according to Horner and Alford's (2019) classification (facilitator, regulator, producer, and buyer). To avoid biases towards

preferred policy options, the author who had been involved in devising several of these policies and in coordinating the focus groups and workshops with Swedish stakeholders was excluded from this selection process.

Our discussion of the effects on GVCs of the six selected policies (addressing our second research question) is not grounded in a direct empirical verification because these policies are still in the making and have not yet been implemented. Instead, we identified their potential effects by triangulating (Yin, 2003) multiple evidence gathered from the aforementioned stakeholders (via dialogues, e-mails, interviews and workshops) with a set of reports by the PLATINEA platform featuring, among others, costs and benefits of many of the six selected policies (e.g., "new reimbursement models" or "mandatory, higher security stocks in the supply chain"). In particular, for this paper's analysis, our interpretations (Alvesson & Kärreman, 2007) of these potential effects relied on matching these multiple sources of evidence with a conceptual understanding of how each policy, thanks to its particular mechanisms to address certain causes of antibiotic shortages, can affect specific theoretically relevant features of GVCs, namely their geographic and organizational dimensions and relations among the GVC links (see the section entitled "Global value chain configurations and resilience" and e.g., Gereffi et al., 2021). Our analysis will also distinguish the focus of the policies, according to three levels which a policy is expected to affect: (a) a single GVC, if aimed at a particular product only; (b) selected GVCs, if aimed at groups of products (e.g., narrow-spectrum antibiotics or children's formulations); or (c) the whole population of GVCs, if applied to the whole market.

Causes of shortages and the antibiotics GVCs in Sweden

Between 2018 and 2024, Sweden experienced 337 antibiotic shortages, with an average length of 150 days and affecting as many as 180 GVCs (Source: Our elaboration of the SMPA open registry of drug shortages[4]). Considering both the general weaknesses of antibiotics GVCs (presented in the section "Global value chain configurations and resilience") and other demand-related issues, about 60 factors contributing to shortages have been identified within the Swedish context (PLATINEA, 2020b). These causes can be grouped into six categories: (1) *buyer and purchasing process*, such as competitive tendering resulting in very low unit prices, no volume commitments, uncertain demand, and purchases fragmented across 21 Swedish counties; (2) *healthcare's use of antibiotics*, such as Sweden's unique prescription patterns, local preferences, and particularly a very restrictive use spread over many different substances; (3) *norms and practices in the field*, such as weak cooperation among stakeholders and lack of supply chain transparency; (4) *seller/MAH's profitability*, such as a small and declining Swedish market, very low margins reducing slack, too many niche products requested, old permits/dossiers difficult to transfer, and costs of inventories; (5) *manufacturing*, such as old, inefficient factories, rigid production, insufficient planning, and restrictions to switch between products (e.g., penicillin causing contaminations); and (6) *supply side*, such as overdependence on a reduced number of API producers, consolidation of factories in a few countries outside Europe, geopolitical risk and preference of API producers to supply larger end-markets (ibid, p. 4). Several of these causes of shortages (especially under categories 3–6) concern characteristics of the GVCs that deliver antibiotics to Sweden, so we now turn to a detailed analysis of these GVCs.

The SMPA database covers the GVCs of all 138 generic antibiotics registered and available in Sweden. Each of these generic products relies on a particular active substance (the main raw materials to produce drugs), provided in a particular formulation (e.g., capsule or vial) and strength (i.e., the amount of active substance in the formulation). Our analysis below presents the main characteristics of the sampled GVCs and how they relate to the risk of antibiotics shortages. We focus on the three main links of the antibiotics value chain: API, FDF, and MAH companies. The dataset includes 367 GVCs, with one or more of them supplying each of the 138 generic antibiotics sold in Sweden. A total of 413 actors operate within these GVCs, in at least one of the three stages. More specifically, 69 MAHs sell the 138 generic antibiotic products which are manufactured by 261 FDF factories starting from active substances provided by 149 API factories.

In terms of governance (Gereffi et al., 2005), among the 367 GVCs, 127 have large multinational MAHs acting as lead firms, with ten in total: Bayer, Fresenius, GSK, Merck, Pfizer, Roche, Sandoz/Novartis, Sanofi, Teva, and Viatris. Thus, 35% of Swedish GVCs belong to the strand of buyer-led "quality generics" according to Haakonsson's (2009, pp. 85–86) categories of drug GVCs governance, whereas the remaining 65% (240) have small MAHs that do not lead the GVC, and would accordingly fall in Haakonsson's category of "low-value generics" lacking a lead firm (ibid, pp. 86–87).

As geography appears among the causes of antibiotic shortages afflicting Sweden and is also a theoretically relevant dimension affecting GVC resilience, Table 1 summarizes the geographic distribution of the actors involved in the three stages, according to the three regions of Europe, Asia, and the rest of the world.

[4] https://www.lakemedelsverket.se/sv/behandling-och-forskrivning/forskrivning/restsituationer/sok-restanmalda-lakemedel

Table 1 Breakdown of sampled actors by GVC stage and geographical location

Region	API producers*	FDF producers*	MAHs
Europe	65	222	68
Asia	74 (China 34, India 29)	26 (China 3, India 18)	1
Rest of the world	10	13	
Total	149	261	69

*Each producer corresponds to a single factory in our database. The same factory may operate at two different GVC stages.

The three stages clearly differ in terms of geographic scope with MAHs and FDF factories characterized by a high level of regionalization (Europe) and the API factories almost equally distributed between two regions: Asia (74) and Europe (65). In terms of supply risk, the high number of API factories concentrated in only two countries of the Asian region (China and India) represents a critical issue. While China focuses almost exclusively on the API stage, India operates in both stages, but is comparatively more involved in the FDF stage. The distance between these Asian countries and the Swedish market implies long delivery times and reduces GVC reactivity to local demand fluctuations, which, in the absence of substantial buffer stocks, increases supply risk. Cultural distance as well as limited transparency involving chain actors who are state-owned (e.g., China, see Ciabuschi et al., 2017; WHO, 2017) or substantially publicly funded (e.g., India, see Government of India, 2020) further increase supply risk in relation to these Asian countries.

To evaluate the risk of antibiotic shortages on the Swedish market and to support our analysis of the potential effects of policies aimed at improving resilience, we conducted a two-step analysis:

(a) (a) First, we focused on antibiotics provided by *only one* MAH, that is by only one GVC. This happens when only one product including a specific active substance (e.g., phenoxymethylpenicillin potassium for Penicillin V) with a given formulation and strength is authorized for sale in the Swedish market. In such a case, no alternatives are available to doctors and patients in case of shortage, since the drug is supplied by only one GVC. Therefore, we refer to these GVCs as *top-risk*. Our database shows that 63 GVCs (17.1% of the total 367) concern products sold by only one MAH.

    For each of these top-risk GVCs we performed a further analysis to consider their geographic and organizational dimensions. A first key assumption is that the higher the geographic concentration, the higher the risk of shortage for the end market. Geographic concentration was evaluated at both country and region levels. Finally, we assumed that greater geographic distance between the API/FDF factories and Sweden, with longer delivery times, imply higher risk of shortage. As for the organizational dimension, we assumed that the lower the number of API and FDF factories involved in the GVC, the higher is the risk (Costantino & Pellegrino, 2010; Ramsay & Wilson, 1990). Consequently, GVCs with low horizontal heterogeneity in their linkages, e.g., only one factory at the FDF stage and the API stage, are characterized by even higher risk, due to the fact that the single FDF and API factories are necessarily located in only one country. Finally, the risk is even higher if these suppliers are located in distant countries/regions.

(b) (b) Then, we focused on the remaining 304 GVCs for products supplied by at least two MAHs. For each of them, we applied again the two dimensions of geographical and organizational configuration to define three levels of risk, namely *high*, *medium* and *low*.

This two-step analysis allowed clustering the 367 GVCs in three categories with risk levels deserving policies against potential disruptions: *top* risk (for products with only one MAH), and *high* and *medium* risk (for products with at least two MAHs).

Starting from the 63 top-risk GVCs with only one MAH providing the respective antibiotic, nine of them have only one API factory and only one FDF factory; therefore, they are characterized by a further level of risk deriving from their minimal horizontal heterogeneity. Relying on single actors inherently entails extreme geographic concentration, as both the sole FDF factory and the sole API factory are located in a single country. Moreover, four GVCs share the same factory for both the FDF and API stages, further heightening the risk in the event of a disruption affecting that plant. As for the geographic dimension of the 63 top-risk GVCs (see Table 2), 14 GVCs (dark grey cells) are characterized by an extreme geographic concentration of

both API and FDF factories in only one country, mainly in the Europe region (ten). Obviously, these 14 GVCs include the nine affected by minimal horizontal heterogeneity as mentioned above.

Moving to the remaining 304 GVCs, they supply 75 antibiotic products (i.e., a specific active substance with a given formulation and strength), each one provided by several MAHs, ranging from a minimum of two to a maximum of ten MAHs per product. When considering the organizational dimension (see Table 3), it emerges that 34 GVCs (dark grey cells) have only one factory at both the API and FDF stages. These 34 GVCs have thus low horizontal heterogeneity and simultaneously also high geographic concentration (being the sole API and FDF factories located in only one country).

Table 2 Breakdown of top-risk GVCs by geographic concentration of API and FDF plants

API factories – geographic concentration	FDF factories – geographic concentration			Total
	Mono-country Europe	Multi-country Europe	Multi-country and multi-region	
Mono country				
Asia	3	2	4	9
Europe	10	8		18
Rest of the world	1		2	3
Multi-country but mono-region				
Asia	3		4	7
Europe	4	3		7
Multi-country and multi-region	8	7	4	19
Total	29	20	14	63

Table 3 Breakdown of multi-MAH GVCs by number of API and FDF factories

Number of API factories	Number of FDF factories						
	1	2	3	4	5	6	Total
1	34 (9.3%)	19 (5.2%)	12 (3.3%)	2 (0.5%)	4 (1.1%)	3 (o.8%)	74 (20.2%)
2	42 (11.4%)	23 (6.3%)	4 (1.1%)	6 (1.6%)	1 (0.3%)		76 (20.7%)
3	23 (6.3%)	17 (4.6%)	6 (1.6%)	3 (0.8%)	3 (0.8%)	4 (1.1%)	56 (15.3%)
4	30 (8.2%)	9 (2.5%)	4 (1.1%)	2 (0.5%)	5 (1.4%)		50 (13.6%)
5	6 (1.6%)	12 (3.3%)	1 (0.3%)				19 (5.2%)
6	8 (2.2%)	7 (1.9%)	1 (0.3%)				16 (4.4%)
7	2 (0.5%)	2 (0.5%)	1 (0.3%)				5 (1.4%)
8	5 (1.4%)						5 (1.4%)
11		3 (0.8%)					3 (0.8%)
Total	151 (41.1%)	94 (25.6%)	32 (8.7%)	17 (4.6%)	18 (4.9%)	13 (3.5%)	304 (82.8%)

Table 4 Breakdown of multi-MAH GVCs by geographic concentration of API and FDF factories

API factories – geographic concentration	FDF factories – geographic concentration			
	Mono-country Europe	Multi-country only Europe	Multi-country and multi-regions including Europe	Total
Mono-country				
Asia	14 (3.8%)	37 (10.1%)	46 (12.5%)	97 (26.4%)
Europe	34 (9.3%)	49 (13.4%)	10 (2.7%)	93 (25.3%)
Rest of the world			1 (0.3%)	1 (0.3%)
Multi-country				
Asia		13 (3.5%)	13 (2.7%)	26 (25.3%)
Europe	20 5.4%)	16 (4.4%)	2 (0.5%)	38 (10.4%)
Multi-country and multi-region	14 (3.8%)	16 (4.4%)	19 (5.2%)	49 (13.4%)
Total	82 (22.3%)	131 (35.7%)	91 (24.8%)	304 (82.8%)

Therefore, they represent the second most risky group of GVCs among the investigated 367 GVCs after the top-risk 63 earlier described. We refer to them as high-risk GVCs; they account for 9.3% of all 367 GVCs. The remaining 40 GVCs supplied by only one API factory and the 117 GVCs supplied by only one FDF (light grey cells in Table 3) have also a certain level of risk as they have only one factory at either the FDF or API steps. We refer to these 157 (40 + 117) GVCs as medium-risk GVCs; they account for 42.8% of all 367 GVCs in our dataset.

The geographic dimension of the 304 GVCs for products which have at least two MAHs (see Table 4) shows that 48 GVCs (dark grey cells) have an extreme geographic concentration because both the FDF and the API factories are located in only one country (mainly in Europe). Thirty-four of these 48 GVCs are the ones earlier classified as high-risk according to the organizational dimension because they include only one factory at both the API and FDF stages. Therefore, the remaining 14 GVCs (48 minus 34), with more than one factory at both the API and FDF stages but located in one country only, can be classified as medium-risk GVCs.

Summing up, our analysis shows that many of the 367 GVCs of Swedish generic antibiotics are affected by a significant level of risk (see Table 5). More specifically, 17.2% are "top-risk" GVCs because their product is not supplied by any other MAH, which makes it impossible to switch to an alternative MAH and its corresponding GVC in case of shortage. Next, a further 9.3% of GVCs are "high risk", due to a low level of horizontal heterogeneity, and 13.1% due to high geographic concentration. Finally, 42.8% are "medium-risk" GVCs due to their low level of horizontal heterogeneity and 48.2% due to their geographic concentration. No matter which GVC dimension (organizational or geographic) and its correspondent overdependence we choose to apply, only about 15% of Swedish antibiotic GVCs can be considered as unaffected by substantial supply risk (low risk). These findings clearly highlight the need for GVC-oriented policies that can address the configurational characteristics of GVCs, which undermine their resilience and may lead to antibiotic shortages.

Swedish policies against antibiotic shortages and their impact on GVCs

To address our first research question, we identified through the process outlined in the "Method" section six policies that are currently under discussion by Swedish policymakers. These are shown in the first column of Table 6 (with the official reports supporting each of them). We now examine these policies individually to answer our second research question about their expected impact on GVCs. In particular, we consider: (a) the causes of shortages and GVC stage they address; (b) their focus (i.e., single GVC, selected GVCs, all antibiotic GVCs); (c) their effects on the organizational and geographical dimensions of GVCs; and (d) their challenges and limitations. This analysis focuses on Sweden as the country aiming to implement these six policies.

Mandatory parallel sourcing

This policy implies spreading antibiotic supply volumes among several suppliers. At the very least, this means that for every antibiotic, two separate MAHs need to be contracted. To further mitigate supply risks, Swedish policymakers may mandate duplication and geographic distribution of upstream supply links, namely the FDF and API steps. To be truly "parallel" the GVCs would need to rely on several FDF factories and even API factories. Intervening at the MAH, FDF, and API stages, this policy aims to address two key causes of shortages: (a) recurrent production problems and (b) overdependence on single actors in particular chain links.

Mandatory parallel sourcing can impact either single or some selected antibiotics, namely those characterized by situations of overdependence. In particular, it could influence GVCs for all products that have one single MAH ($N = 63$), one single FDF factory ($N = 100$) and one single API factory ($N = 177$). Overall, a structural effect is an increase in the number of GVCs, but not necessarily in the number of total actors at every link of the GVC. The number of MAHs will likely increase because 63 of 138

Table 5 Breakdown of 367 GVCs by level of risk

Level of risk	No. of MAHs	Source of risk	Horizontal heterogeneity	Geographic concentration	No. of GVCs	Percent of 367 GVCs
Top	1	Only 1 MAH	Mixed	Mixed	63	17.2%
High	>1	Only 1 API factory *and* only 1 FDF factory	Low	High	34	9.3%
		API *and* FDF factories located in only 1 country	Mixed	High	48	13.1%
Medium*	>1	Only 1 factory at *either* API *or* FDF step	Medium	Mixed	157	42.8%
	>1	API *or* FDF factories located in only 1 country	Mixed	Medium	177	48.2%

*A single GVC can be affected by both types of risk and hence fall in both rows

Table 6 Six selected policy options; impact on GVCs and limitations

Policy option	Addressed causes of shortages (and GVC stage)	Focus of effect	Impact on GVC's structural dimension	Impact on GVC's geographic dimension	Challenges and limitations
1. Mandatory parallel sourcing (Sources: PLATINEA, TLV, Technopolis, EHO, Swedish EU Presidency)	Recurrent production problems, overdependence on single chain links (MAH, FDF, and API)	Single or selected GVCs	High	Medium-high	Increased costs, complex coordination, changed routines, finding suppliers
2. Mandatory security stocks (Sources: PLATINEA HERA, TLV, Technopolis, EHO)	Limited planning ability of drug suppliers, uncertain demand, low price, limited slack in GVCs (MAH, FDF, and API)	Selected or all GVCs	Medium (relational)	Low	High inventory and administrative costs, risk of wastage
3. Facilitate factory change (Sources: PLATINEA, Technopolis)	Old factories, too expensive to upgrade to new standards, rigid production systems, difficult-to-transfer old permits (API and FDF)	All GVCs	Medium (relational)	Medium	Costs for public authorities, unclear minimal requirements, suboptimal plants, and price increase
4. Relocate antibiotic production near the end market (Sources: PLATINEA, HERA, WGEMA, Swedish EU Presidency)	Fewer European producers, few and geographically concentrated API suppliers, too few distant suppliers, geopolitical risks (API and FDF)	Single or selected GVCs	High	(Very) high	Large investments, larger than needed production volumes, infringing state aid rules, negative effects on competition
5. Improved information sharing and transparency along the supply chain (Sources: PLATINEA, HERA, TLV, Technopolis, Swedish EU Presidency)	Lack of transparency and of communication between stakeholders (primarily MAH)	All GVCs	Medium (relational)	Low	Costly IT system integration, need to agree on standards, new complex routines, confidentiality, legal issues
6. New reimbursement models (Sources: PLATINEA, TLV, EHO, WGEMA, Swedish EU Presidency)	Ineffective price-driven models, no commitment, insufficient return (MAH)	Single or very selected GVCs	High (relational)	Medium	Complex to administer, difficult product selection, effects on competition

generic antibiotics sold in Sweden are supplied by only one MAH and one GVC. Instead, the number of FDF and API factories may remain the same for any given antibiotic, though they will need at least another matching factory in the same chain. Basically, the same two FDF factories can operate on two different GVCs supplying the same antibiotic. Therefore, an important effect is relational because otherwise competing actors (e.g., two API factories) will need to coordinate production volumes, deliveries, and technical issues. The further requirement that FDF and API factories should be located in different countries would affect as many as 221 GVCs (60%) with API producers in a single country and 111 GVCs (30%) with FDF producers in a single country, but especially the 62 GVCs (16.8%) with both FDF and API links in a single country. The overall effect is to make each chain more geographically spread out in terms of combinations between its vertical links. The potential limitations of this policy are increased direct and indirect (administrative) purchasing costs for public healthcare, including complex coordination of suppliers, and challenges such as new routines for purchasers and finding alternative suppliers.

Mandatory security stocks in the supply chain

To prevent stock-outs, this policy includes variants such as mandatory increases in revolving operative stock levels across the value chain and strategic stockpiles held separately by public authorities for emergencies. Here, we focus on operative stocks maintained by MAHs, FDF, and API factories. The two key dimensions of this policy are the volume increase required and the geographical location, with inventories closer to the end market (at distributors and MAHs) being more effective in preventing shortages. This is particularly relevant for Sweden, which lacks domestic antibiotic production. Considering this issue, a recently introduced Swedish fixed yearly reimbursement for exclusive (i.e., non-generic) antibiotics mandates that MAHs maintain 6 months of stock in Sweden. This policy intervenes potentially at all stages of GVCs (MAH, FDF, and API) and addresses shortages caused by uncertain demand, limited supplier planning, and low antibiotic prices, which discourage slack in GVCs. In fact, for high-priced products, MAHs already hold larger stocks to avoid revenue losses from stock-outs.

This policy targets selected or all antibiotics rather than a single one and is unlikely to significantly alter the number of actors or the structure of Swedish antibiotic GVCs. However, certain selected actors will need to manage increased inventories. If stocks are held in Sweden, MAHs must expand storage capacity, potentially outsourcing to local logistics partners. With only two authorized drug distributors in Sweden, their capacity may also need expansion. If stocks are held abroad, foreign FDF or API factories will bear the increased inventory burden. High costs may lead some MAHs to withdraw products unless adequately compensated. Geographically, GVC configurations are expected to change minimally. However, power may shift toward actors managing the expanded inventories, especially if stock volumes reach up to 6 months of normal consumption. This could lead MAHs to strengthen control and coordination with offshore FDF and API factories to ensure stock deployment when needed, e.g., in case of epidemics or supply disruptions. Challenges associated with this policy include increased inventory costs, disputes over cost allocation, higher administrative and coordination expenses, and risks of product expiration, leading to higher wastage.

Facilitate factory changes post-approval

This policy facilitates transferring older production files, tied to specific factories since drug approval, to new facilities. Regulatory agencies require these files for production approval, but older files often lack the data needed for such transfers. By enabling smoother and more cost-effective site changes at both API and FDF stages, this policy could boost overall production capacity. It addresses several causes of antibiotic shortages, particularly related to the rigid production systems, outdated factories that are too costly to upgrade, and challenges in transferring old permits to newer facilities. The main benefit is reducing deregistration, as MAHs often withdraw antibiotics when production transfers are too expensive or complex, while also preventing stockouts by utilizing modernized facilities.

This policy applies to all antibiotics and aims to simplify the creation of parallel chains or allow MAHs to shift production phases to other factories. By reducing switching costs, it fosters competition among FDF and API factories, potentially encouraging less efficient factories to upgrade. While it is uncertain if competition will also lead to factory closures, the number of available factories is likely to grow, enhancing GVC flexibility and the formation of new ones. Geographical shifts are difficult to predict, as technology transfers can occur within or across continents. The policy promotes horizontal communication (and transfer of registry documentation) among GVC actors. Another relational effect of this policy is the reduced dependency of MAHs on individual FDF or API factories, weakening the power of these factories thanks to reduced switching costs. Challenges related to this policy include higher public costs, lengthy updates to regulatory standards, and potential acceptance of suboptimal factories or increased antibiotic prices.

Relocate antibiotic production closer to the end market

This policy focuses on relocating specific value chain steps, such as FDF or API production, or entire chains closer to the end market. Relocations can range from nearshoring (within Europe or the Nordic countries) to backshoring (to Sweden). Tools for relocation include financial incentives for firms or direct state investment in publicly owned factories. These efforts vary in state control, from fully private to state-owned or jointly funded plants. While intervening at the FDF and/or API stage, this policy addresses several causes of shortages: the decreased number of European producers (Fischer et al., 2023) which, together with the reduced number and high geographic concentration of API suppliers, leads to a strong dependence on too few and distant suppliers, entailing in turn substantial geopolitical risks for a country like Sweden. The desired potential benefits are: less dependence on volatile global markets, reducing supply risk and stock-outs, adapting production to local needs, as well as avoiding deregistration by having suppliers more committed to the home market.

This policy focuses on single or selected antibiotics, rather than all antibiotics. It targets overdependence on offshore production, affecting about 30% of Swedish antibiotic GVCs (108 of 367, see Tables 2 and 4, sum of first row in both tables), which rely entirely on API factories in China or India. However, with no Swedish API producers, backshoring API production to Sweden is economically unfeasible due to costs exceeding the total Swedish antibiotics market (~€50M/year). Hence, massive public subsidies would be required to make this viable. It is instead more feasible to backshore the FDF stage of some GVCs as there is currently one FDF factory in Sweden running with spare capacity. However, the maximum capacity of this FDF facility may be reached with a handful of additional product assignments, requiring it to expand its capacity or establish a new FDF factory. This would require public investment or long-term contracts with public buyers. Consequently, nearshoring FDF or API production to other European countries is a more feasible option from a financial viewpoint. European API and FDF factories have sufficient spare capacity to support Swedish GVCs without substantial subsidies.

The nearshoring option concerns 78 API factories, 74 in Asia, and four in the rest of the world (i.e., about 50% of all API suppliers to Sweden). This policy will reduce these numbers by a share that depends on the size and attractiveness of incentives provided to MAHs to make this geographical adjustment of their GVCs. A likely relational effect is stronger relationships between MAHs and nearshored FDF and API factories due to larger business volumes. However, relationships with Asian FDFs and APIs may terminate or worsen due to their loss of interest in smaller production assignments, which can lead to reduced variety of supply. There are several challenges and limitations related to this policy: the large amount of public and private investments required, especially if involving API production; and the risks of infringing EU rules on state aid and of producing unexpected negative effects on competition.

Improved information sharing and transparency across the supply chain

This policy seeks to enhance information sharing across the supply chain, including updates on consumption levels, anticipated needs, stock levels, and production capacity at each stage. Interconnected IT systems could provide "early warnings" of shortages by identifying mismatches between production orders, inventories, and demand. By reducing uncertainty and supply risks, this policy aims to minimize stock-outs. This policy would also provide support to other policies, especially #2 about security stocks (by indicating their location and levels, possibly in real-time) and #3 about factory changes (by supporting the transfer of files between actors).

This policy applies to all antibiotics and aims to increase transparency regarding the location, conduct, and performance of FDF and API factories. While involving all stages of GVCs, this policy especially affects MAHs. Greater transparency may prompt MAHs, concerned about public perception or regulatory scrutiny, to shift production from outdated, high-pollution, and high-risk factories, many of which are low-cost facilities in Asia. This shift could favor European factories or higher-standard Asian facilities, pressuring lower-standard factories to upgrade to avoid losing assignments. Considering also the barriers to transparent communication with state-owned actors (e.g., in China) or substantially state-funded actors (e.g., in India), the overall structural impact of this policy is that fewer FDF and API factories will remain available for MAHs to include in GVCs for Sweden, with the extreme situation that some GVCs will need to be terminated. Geographically, the policy is expected to increase European participation in GVCs and improve the standards of selected Asian factories. This policy fosters better vertical coordination within GVCs and stronger relationships across their links by enhancing information flows between end users and raw material suppliers. However, challenges include high costs and the time required to integrate disparate IT systems, the need for standards and definitions (e.g., of what constitutes a supply disruption), and developing new routines and communication processes. Additionally, some stakeholders may resist sharing confidential information due to competition concerns, antitrust risks, or legal barriers.

New reimbursement models

This policy for *generic* antibiotics is based on Sweden's 2020 revenue guarantee scheme for *new* antibiotics still covered by exclusivity. That policy is a revenue guarantee scheme that pays a fixed yearly amount of about €400,000 irrespective of unit sales levels. This scheme allowed the PHAS to have five new antibiotics registered in Sweden considerably earlier than MAHs would have done, even earlier than in larger European countries. Regarded as successful by both PHAS and participating companies, PHAS is now devising a similar model for generic antibiotics as follows: The new policy may offer MAHs fixed yearly payments of at least €100,000 per selected antibiotic under 1- or 2-year contracts. PHAS has identified 20 antibiotics for inclusion, targeting products in the Access and Watch categories of the WHO's AWaRe classification (WHO, 2023). These antibiotics were selected from a list of 130 products deemed critical by Swedish clinicians due to their high medical value and risk of shortages. Intervening specifically on MAHs, this policy addresses shortages caused by insufficient supplier returns due to intense price competition and the absence of long-term customer commitments.

This policy focuses on single or very specific antibiotics and so far, has received positive feedback from MAHs and FDF actors. While this scheme does not offer direct payments to FDF actors, they benefit from keeping production volumes for products that might otherwise be deregistered and from a share of MAHs' increased revenues. Renewable yearly contracts under this reimbursement model strengthen relationships between MAHs and upstream GVC links, as well as between MAHs and public awarding bodies. The policy's contractual conditions, such as rapid and accurate deliveries, may prompt MAHs to prioritize FDF and API factories closer to Sweden, likely increasing the presence of European factories in Swedish GVCs. Benefits include reduced uncertainty and supply risks, incentivized registration, and stock-out prevention through mandatory security stocks (funded by the government) and shortage prevention plans, supporting also the policies on security stocks (#2) and information sharing (#5). Challenges include administrative complexity, difficulty selecting products, and potential supplier reactions, along with risks of unintended negative impacts on competition.

Comparing the six selected policies (see Table 6), those with the strongest potential impact on GVCs are numbers 1, 3, 4, and 6. In particular, mandatory parallel sourcing (#1) and relocation (#4) can have a high impact on both the organizational and the geographic configuration of GVCs. New reimbursement models (#6) are a particularly interesting policy because, although they can be applied only to a restricted number of antibiotics, they can have a strong impact on GVC configurations. Policies also vary in terms of their focus (single, selected or all GVCs) – four out of the six policies would impact only selected or even single GVCs – suggesting that policymakers can adopt a more granular view and also target specific GVCs to tackle the problem of shortages. Two of the six policies also support the others, namely policy #5/Transparency enables both #2 (mandatory inventories) and #3 (factory change), and policy #6/New reimbursement supports #2 and #5 (transparency).

Discussion of findings

Based on our findings, we now discuss the key mechanisms to improve GVC resilience and the role of the state in each policy (Horner, 2017; Horner & Alford, 2019). We then examine how these policies differ when implemented at the EU level as opposed to the national level (e.g., Sweden), thereby addressing our third research question. Finally, we consider the implications of different types of GVCs governance (Gereffi & Korzeniewicz, 1994; Gereffi et al., 2005; Haakonsson, 2009) for the selected policies and their relevance for other small high-income countries like Sweden (Crowe & Rawdanowicz, 2023; Lanz & Werner, 2018).

Enhancing resilience: Policy mechanisms and roles of the state

The resilience of antibiotic GVCs can be enhanced through policies that leverage different mechanisms and define specific roles for the state. A first group of policies intervenes on GVC resilience by *multiplying* GVCs. For example, mandatory parallel sourcing would expand the number of GVCs and diversify supply links, creating greater variety and heterogeneity in supply (Miroudot, 2020; Pietrobelli et al., 2021). However, horizontal coordination is essential for this policy, affecting not just the number and location of GVC actors but also their relationships. With mandatory parallel sourcing, the Swedish state would play a key role as a regulator of purchasing procedures, mandating changes in the behavior of GVC actors, particularly MAHs and public healthcare purchasers. Additionally, the state could act as a strategic buyer, using incentives and selection criteria in tendering processes to enforce this policy. Facilitating factory changes within and between GVCs is another policy that would multiply GVCs and create more flexible link combinations, providing alternatives to address rigidities (ibid). The state in this policy can take two specific roles: facilitator, offering expertise and assistance through agencies like the SMPA; or regulator of production processes, simplifying regulatory requirements to enable smoother factory changes.

Other policies aim instead at *reinforcing existing* GVCs. For instance, mandatory security stocks would create additional slack resources, such as larger inventory levels. In

this policy, the Swedish state would act as the regulator of logistics practices, setting national rules on inventory levels and locations. Via the same policy the state could also act as strategic buyer, either directly by maintaining its own larger stockpiles or indirectly by paying other GVC actors to do so. Information sharing and transparency is another policy that strengthens resilience by reinforcing GVCs in terms of improved coordination among actors and easier selection of more reliable factories. Under this policy, the Swedish state would play two roles: facilitator, with public authorities sharing critical data such as stock levels and consumption; and regulator of communication procedures, requiring GVC actors to disclose essential information, including production capacities and potential shortages.

Reinforcing existing GVCs is the mechanism to improve resilience also of new reimbursement models, by providing greater financial resources and longer commitments to GVC actors. However, this policy also exploits an additional mechanism, namely *gathering* GVCs closer to end customers due to requirements of rapid and precise deliveries. Gathering GVCs is obviously the mechanism also of the policy to relocate antibiotic production closer to the end market, as a way to increase control over manufacturing (Elia et al., 2021; Pegoraro et al., 2022). Through new reimbursement models, the state would assume primarily the role of buyer, via tendering and purchasing contracts, and of regulator of purchasing/logistics procedures, via mandatory clauses for suppliers. With relocation, the state would instead take the role of facilitator, by incentivizing nearshoring/backshoring, or of producer, by possibly owning production plants.

Summing up, the mechanisms through which policies improve GVC resilience can be categorized as *multiplying GVCs*, *reinforcing existing GVCs*, and *gathering GVCs*. These three mechanisms can be used at the same time, i.e., they are not mutually exclusive, as they would be instead for a single GVC and lead firm, and they vary in their focus of intervention, i.e., single, selected or many GVCs.

Additionally, each policy implies distinct roles for the state, ranging from regulator (of specific activities) to facilitator, and from buyer to producer (see Horner, 2017; Horner & Alford, 2019). These findings advance the understanding of the different roles the state can play in relation to GVCs (Horner, 2017, 2022) by showing which particular policy entails which role (see also Table 7). Interestingly, these roles seem to be context-dependent: Sweden takes first the buyer role (via policies closer to implementation such as the new reimbursement model and mandatory stocks), followed by regulator and facilitator, leaving to the last, as *extrema ratio*, the role of producer (relocations). This basically reverts the sequence followed by South Africa to achieve the same goal of improving access to drugs (Horner, 2022), thus emphasizing the importance of contextual factors for GVCs studies, such as Sweden's lack of local producers (like South Africa) but strong public healthcare system (differently from South Africa).

Comparing Sweden to the EU level

Addressing our third research question, we now examine the potential differences the six policies present if applied at the EU level compared with Sweden.

Mandatory parallel sourcing would differ significantly between the two contexts. In Europe, the number of GVCs is higher due to a larger number of MAHs. Unlike Sweden, which has only one FDF factory, Europe has many FDF and API factories, particularly in Italy and Spain, with numerous GVCs entirely within the EU. Therefore, for the EU market, fewer antibiotics may require additional parallel MAHs or chains and most chain links could likely be duplicated within the EU, unless extra-EU links are mandated in the policy. Overall, the structural and geographical impact on the many

Table 7 State roles, resilience-enhancing mechanisms, and regional changes for the selected policies

Policy option	State role	Mechanism to improve resilience	Size of changes Sweden vs. EU (small/large)
1. Mandatory parallel sourcing	Regulator and buyer	Multiplying GVCs	Large
2. Mandatory security stocks	Regulator and potential buyer	Reinforcing existing GVCs	Large
3. Facilitate factory change	Facilitator and regulator	Multiplying GVCs	Small
4. Relocate antibiotic production near end market	Facilitator and potential producer	Gathering GVCs	Large
5. Improved information sharing and transparency	Facilitator and regulator	Reinforcing existing GVCs	Small
6. New reimbursement models	Buyer and regulator	Reinforcing and gathering existing GVCs, multiplying GVCs at the EU level	Large

GVCs supplying the whole EU market is likely smaller than on the fewer GVCs supplying only Sweden.

For *mandatory security stocks*, a main difference between the single state and the EU, is that stocks can be placed in a wider range of locations, wherever MAHs or FDF and API factories operate. However, this flexibility introduces challenges, as some EU countries may oppose stocks being held elsewhere, fearing they could be deprioritized during disruptions. A European policy would therefore require a mechanism to ensure rapid deployment across all EU countries, regardless of stock location. The geographical impact on GVCs is hard to predict because security stocks will likely be stored in countries offering the best balance of storage costs and deployment speed, making peripheral locations less favorable.

Facilitating factory changes post-approval would require no substantial changes if applied by the EU, except that it would affect many more FDF and API producers as there are many more GVCs delivering to all of Europe than to just Sweden. Within a broader pool of factories and more MAHs supplying Europe, it is likely that more technology transfers will occur.

For *relocations of production closer to the end market,* the distinction between nearshoring and backshoring becomes irrelevant at the EU level, but for individual countries it remains significant. Whether a country is chosen to receive relocated production depends largely on the presence of API or FDF factories. Public subsidies or investments are likely to prioritize expanding current facilities rather than building new ones. Unlike in Sweden, MAHs at the EU level have access to a wider range of European factories. These facilities are more easily mobilized to join GVCs or expand capacity because the larger sales volumes across the EU market make such investments more financially viable, often without substantial public subsidies. Thus, an EU-level relocation policy may not be as interventionistic as for Sweden (which needs co-investments, subsidies or at least public long-term contracts) and may work with other triggers, such as public tender requirements of "made in Europe". From a relational viewpoint, we can thus expect less dependence of MAHs on public buyers.

The policy requiring *information sharing and transparency across the supply chain* would have the same effect at the EU level as for Sweden, i.e., increasing the share of European FDF and API factories in GVCs, reducing dependence on Asian factories. However, facing a larger European market may incentivize more Asian factories to upgrade to continue supplying it. An EU-wide approach could also facilitate sharing data on performance, stock levels, and demand across GVCs. This opens opportunities for horizontal connections between "parallel" GVC links, allowing inventories from different MAHs or FDF factories to be compared, deployed, or transferred to address disruptions in specific countries. While supporting also policy #2 (security stocks), these expanded horizontal relationships across GVCs would compensate the potential risk mentioned for the Swedish case that the number of viable GVCs decreases due to a lack of acceptable FDF and API factories following increased transparency requirements.

Finally, adapting Sweden's *reimbursement models* to the EU faces the challenge that a single MAH can hardly make the commitment to supply all 27 EU countries with a generic antibiotic. A proposed solution is to grant fixed yearly payments to one or two FDF producers instead of MAHs (Årdal et al., 2023). These FDF producers would then coordinate with multiple MAHs, assigning them responsibility for specific countries. This adjustment would have significant relational and structural impacts on GVCs. Relationally, power would shift to FDF producers, who would lead the GVCs instead of MAHs, defining therefore a new strand of drug GVCs next to the three identified by Haakonsson (2009). Structurally, many GVCs would be newly formed, as the awarded FDF producer would likely need to involve new MAHs to ensure coverage across the EU. While the GVCs would center around the same FDF producer(s), the number of GVCs would increase as a result, making the new reimbursement models the only policy capable of exploiting *all three mechanisms* to improve resilience (multiplying, reinforcing, and gathering), when considering both the national and the EU levels.

Summing up our discussion on the comparison between the Swedish and EU contexts, four out of six policies entail substantial changes in terms of application and effects (see Table 7). For instance, mandatory parallel sourcing (#1) faces many more and more diversified antibiotics GVCs at the EU level and thus implies quite different effects. New reimbursement models (#6) and relocation (#4) have a very different context at the EU level, requiring coordination among many states and greater complexity in implementation. Moreover, shifting from the Swedish to the EU context can have the particular effect of expanding the mechanisms of a policy to improve resilience, as we have seen for new reimbursement models.

By disentangling key differences at the national (Sweden) versus regional levels (the EU), we observe significant variations in complexity and coordination requirements for the selected policies. While some policies (e.g., factory changes post-approval and improved information sharing) require minor changes, others (e.g., parallel sourcing, relocation of antibiotic production, and new reimbursement models) become more complex at the EU level, requiring more coordination efforts and causing competition between countries. This highlights how the impact of the policies is framed by the *different contexts surrounding the policies and the single GVC*, not only national versus regional contexts, but also different or similar countries.

Relevance for other small high-income countries and different types of GVCs

After discussing how the selected policies would change when moving from the Swedish to a very different context like the EU, we now consider the relevance of these policies in a more similar context, that is, other small high-income countries like Sweden. Specifically, we focus on the implications that different types of antibiotic GVC governance structures (Haakonsson, 2009) have for the bargaining power of these countries (e.g., other Nordic countries, see WGEMA, 2022) and hence on the effects of the selected policies in these contexts.

The policy about mandatory parallel sourcing may not bring the expected effects on "quality generics" GVCs (Haakonsson, 2009) led by large multinational MAHs, as the latter have substantial bargaining power compared to the (limited power of) countries with small domestic market. A similar issue holds for the mandatory security stocks policy, for which MAHs would require compensation: large MAHs leading "quality generics" GVCs and selling their products in several countries, including the largest ones (e.g., Germany and Italy), would possibly require higher compensation than smaller MAHs, thanks to their comparatively stronger bargaining power. However, for countries with a majority of "low-value generics" GVCs like Sweden (65%), that would be less of a problem.

The policy facilitating factory changes could be quite effective for "quality generics" GVCs because these are led by large multinational MAHs, who often operate at different stages of the GVC and have more than one plant available for each drug's production process phase. However, the same policy can be attractive also for "low-value generics" GVCs (ibid.) where smaller MAHs integrate supplies from an open market because the latter's bargaining power towards FDF and API suppliers would increase thanks to reduced switching costs. As this policy would be well received by both types of GVCs, it represents a particularly relevant option for small high-income open economies like Sweden, allowing them to support both types of GVCs and keep both of them as available sourcing alternatives.

Relocating antibiotic production is a policy whose effects clearly depend on the size and other contextual features of the country pursuing it. As mentioned, the backshoring alternative may prove too costly for a single small high-income economy to support via public investments. Nearshoring is a more feasible alternative for small high-income countries and could involve joint financial assistance from other similar small economies, such as Nordic countries for a Swedish relocation policy (see Baraldi et al., 2023). A nearshoring alternative may include contributions from the country hosting the new plant and the other small, high-income countries that would benefit from its outputs. While negotiating such an inter-governmental policy may prove complex, it would offer several small countries acting jointly a stronger bargaining position *vis á vis* also the largest MAHs leading "quality generics" GVCs.

Improving information sharing and transparency is a policy that has been successfully introduced already by a high-income country even smaller than Sweden, namely New Zealand (Årdal et al., 2021), showing that small countries can indeed induce large MAHs to make information about their GVCs public. This policy is more likely to have effects across "quality generics" GVCs because they are led by powerful MAHs who can influence the other actors involved in the chain, especially if vertically integrated. Finally, new reimbursement models are clearly an attractive option for small high-income countries to improve their access to antibiotics and avoid shortages by using their spending capacity to compensate their small market size with better payment terms to MAHs. Indeed, this allowed Sweden to obtain access to certain antibiotics earlier than several larger European countries (see the section entitled "Swedish policies against antibiotic shortages and their impact on GVCs"). As a further detail, the MAHs that joined the previously piloted Swedish model (for new antibiotics) were both large MAHs and smaller MAHs, suggesting that new reimbursement models can affect both strands of Swedish antibiotic GVCs according to the typology by Haakonsson (2009).

Conclusions

Our findings about Sweden might apply to other high-income countries because they face similar challenges and causes behind shortages, such as overdependence on just a few Asian API suppliers, and lack of profitability and transparency in supply chains (FDA, 2019; Anderson et al., 2023; 27–9). Reacting to this situation, other countries have introduced or are considering policies similar to those we discuss for Sweden. For instance, the UK has introduced a subscription model similar to the Swedish one (see policy #6), and the EU's Health Emergency Preparedness and Response Authority (DG HERA) is considering policies similar to the Swedish ones, especially security stocks (European Commission, European Health and Digital Executive Agency, 2022). In particular, the potential effects of policies on GVCs that we identify for Sweden would also hold for other high-income countries, which have similar healthcare systems and face the same type of GVCs in terms of governance (see Haakonsson, 2009). Our discussion suggests that the context to which policies are applied needs to be understood at the level of GVCs because variations in GVC governance can imply different effects for the policies pursued by other small countries like Sweden.

The GVC literature has shown the fragility of GVCs during recent disruptions (e.g., Gereffi et al., 2022; Pananond et al., 2020; Panwar et al., 2022), but has taken mostly the firms' perspective on how GVCs can be made more resilient. Our paper complements this perspective by examining how public policies can influence GVCs and their resilience. Our conclusions cover first the implications of our study's change in perspective for the literature on GVCs, international business and policy, as well as for policymakers. We then propose avenues for further research, considering how GVCs and policies in other strategic sectors can face disruptions related to today's rising geopolitical tensions (Moradlou et al., 2025).

Theoretical implications

This paper contributes to the GVC literature by showing the benefit of taking a policy perspective when studying GVCs. We provide a nuanced view of how policies can impact GVC configurations in terms of organizational and geographic dimensions, as well as the relationships between GVC links. Our findings show how a set of targeted policies does not have single effects on GVC configurations, that is, *either* increasing control and geographical vicinity of GVCs (Kamakura, 2022; Pedroletti & Ciabuschi, 2023) *or* making GVCs more globalized and diversified (Jiang et al., 2022; Miroudot, 2020). Instead, policies may affect GVCs in both directions. We also show that policy can affect single as opposed to multiple GVCs. Interestingly, the three policies with highest potential impact (parallel sourcing, relocations, and reimbursement models), focus on single or few GVCs, while the other three policies addressing many or all GVCs have lower potential impact. Moreover, our analysis of Swedish antibiotic GVCs identified as sources of supply risk two specific dimensions of GVCs, namely *low horizontal heterogeneity* (a low number of actors operating in each link) and *geographic concentration* (co-location in a country of all actors operating in a given link). Finally, our findings show that the impact of policies on GVCs also depends on their *governance* according to the types proposed by Haakonsson (2009). Policies for other sectors can be analyzed and devised by considering explicitly these three dimensions of GVCs.

By further delving into the perspective of policymakers (e.g., a country), we identify three key mechanisms that explain how policies can support GVC resilience: (a) *reinforcing a single GVC*, via e.g., higher inventories, improved payments from public procurement, and transparency or communication among GVC partners; (b) *gathering GVCs*, that is, bringing them geographically closer to policymakers, e.g., via reshoring or other relocations; and (c) *multiplying GVCs*, that is, creating multiple and geographically diversified GVCs, e.g., via parallel sourcing and broadening the number of producers. These mechanisms are a novel and valuable tool for researchers to further explore the impact of policy in other essential GVCs whose resilience needs to be increased. Our findings advance also our understanding of the different roles the state can play in relation to GVCs (Horner, 2017, 2022), stressing that these roles are context-dependent, i.e., specific for the Swedish case, and therefore differ from previous research (e.g., roles in the South African context, Horner, 2022). Finally, our findings stress that policies by small high-income countries can be more or less effective depending on the governance type of GVCs (Haakonsson, 2009). For instance, "quality generics" GVCs may be more difficult to affect because of the bargaining power of their lead firms, than "low-value generics" GVCs, which lack lead firms.

For the international business literature, our study supplements research on the effects of recent crises on regionalization (e.g., Enderwick & Buckley, 2020) and extends the logic of regional versus global strategies (e.g., Rugman & Verbeke, 2004) by underlining the role of policy in addressing supply risk. Two of the policies examined specifically address near- and backshoring and parallel sourcing, contributing to the discussion within international business on (re)location, geographical spread, and resilience of GVCs. Notably, when comparing backshoring and nearshoring, our analysis shows that, for countries with small internal markets like Sweden, backshoring may be less attractive to justify the investment required for relocating production activities (Baraldi et al., 2023). This aligns with Barbieri et al. (2020), who argue that location decisions should sometimes be evaluated at a regional level, i.e., the EU. These findings can be generalized to other industries facing similar shortages, especially for small countries considering regional vs. country-specific policies.

Finally, our analysis offers important contributions to international business policy research. First, following the framing by Van Assche and De Marchi (2024), we enhance our understanding of the link between public policy actions and international business phenomena (i.e., GVCs). Specifically, in the context of the challenges posed by antibiotic shortages, we show how a set of policies can influence the configurations and resilience of GVCs by acting through three different mechanisms. Second, we disentangle key differences between the policies if applied in a single country (Sweden) and at the regional level (the EU). In fact, while some policies require minor changes, others become much more challenging when considered at the EU level. This suggests the need for coordination between national and regional levels and to consider if a policy option can indeed be pursued at the regional level.

Implications for policymakers

This paper offers insights to policymakers involved in reducing the risk of antibiotic shortage, either at the national or supra-national level. We recognize the specific challenges of small high-income countries, which are overdependent

on GVCs and face difficulties in attracting reliable supplies due to the limited size of their internal markets, and show how policies can impact antibiotic GVCs by affecting their organizational and geographic dimensions. In particular, policymakers should specify which supply risks and problems are particularly serious in the GVCs at hand (e.g., low horizontal heterogeneity and/or high geographic concentration) and then devise policies capable of addressing them. Policymakers are also advised to consider the linkages between national and regional policies. Certain policies are easier to apply in a single country (e.g., increased security stocks or new reimbursement models), while others are easier or more relevant at the EU level (e.g., parallel sourcing and relocations). This insight can help both divide the responsibility between single countries and the EU (selecting policies to be kept at the country level) and stimulate collaboration between single countries and the EU. In this regard, EU policymakers should evaluate how EU policies match single countries' needs.

National and regional policymakers should also consider how GVC links can be reinforced (Pietrobelli et al., 2021) while creating both *economic* and *social* benefits. Some policies can promote partnerships between private actors and public ones, which represent social values. For instance, public actors can collaborate with MAHs to upgrade their GVC as described in our analysis. Economic benefits are instead essential drivers for private firms to reinforce their GVCs. Therefore, policies should be devised so to allow firms to improve economic performance in multiple ways: market forces (e.g., increased supply chain transparency stimulating competition), contracts enabling more reliable revenue streams (via e.g., new reimbursement models), or even more direct state intervention, such as subsidies or even co-financing (e.g., in factories involved in relocations).

Future research

Our study focuses on the field of antibiotics and the Swedish context. Therefore, our analytical approach and results need validation in and comparison with other industrial and national contexts that also suffer from significant shortages. It would be particularly valuable to extend this study to other pharmaceutical products, as both the US and EU[5] governments currently reclassified pharmaceuticals as a strategic sector for national security, similar to semiconductors and energy resources. Additionally, governments often view strategic sectors as instruments of economic and political leverage and may implement tariffs, sanctions, or investment controls to achieve diplomatic or strategic ends (Buckley & Strange, 2015). Given the increasing political tensions and trade conflicts, policymakers perceive current overdependence on adversarial economies for essential medicines to be risky (Guinea & Sharma, 2022) . Therefore, we warrant future research to consider the potential development and effects of new policies (e.g., strengthening regional pharmaceutical hubs in the US and EU) also for other pharmaceutical areas – or even other strategic sectors – that present similar GVCs risks.

One limitation of our study is that the analyzed policies have not yet been implemented. Indeed, most of them are still in the making, and hence it was not possible to observe their actual effects. To address this limitation and avoid waiting for several years before the effects become visible, further research can apply computer-based simulations (e.g., agent-based modelling) to model GVCs and simulate the effects of various policy options on drug shortages and specific GVC links. We delimited our study to analyze the effects of policies taken one by one. However, several policies can be introduced together and thereby rely on potential synergies. Our study shows, for instance, that two of the six policies support the other three policies. Therefore, future research should also consider the combined effect of policies acting together on GVCs.

While exploring potential effects of future policies can help policymakers, De Marchi and Alford (2022) highlight that policy design and implementation are important mediators of the actual effects on GVCs. Therefore, future research should include policy implementation studies, penetrating into the barriers, especially legal ones (e.g., potential conflicts between national and EU-level regulations), and adopting longitudinal perspectives, as policies require considerable time to be adopted and effects take time to materialize. Finally, a key element in policy implementation is the actor who takes responsibility and drives the process, which can be a private actor (e.g., an MAH switching FDF factories), a public buyer (e.g., granting fixed yearly payments), or even a regulator (e.g., requiring national or regional production to register a drug). Further research should accordingly consider explicitly the level of interventionism in each policy, analyzing clearly the role of the state and other public authorities in policy implementation as opposed to the role of private actors.

Appendix

See Table A.

[5] E.g., The White House Executive Order on America's Supply Chains (2021), which includes the funding for domestic API production and boost critical medicine manufacturing; the EU Pharmaceutical Strategy (2020) promoting domestic drugs' manufacturing.

Table A Interviews on antibiotic supply chains and policies against shortages

Date	Organization or organization type	Interviewee	Topic
2024–03–14	EU-level antibiotic access project (EU-JAMRAI 2)	Work-package coordinator	Status of EU-level revenue guarantees for new and old antibiotics
2024–03–07	Public Health Agency of Sweden	Project manager	Proposal for Swedish model of revenue guarantee for old antibiotics
2023–12–18	Public Health Agency of Sweden	Expert advisor	Comparison of Swedish policies to improve access to antibiotics with other Nordic countries
2023–12–14	EU-level agency for drug access (DG HERA)	Policy officer	Plans for an EU-level revenue guarantee for newly approved antibiotics: structure and conditions
2023–09–12	Association of European generics suppliers (Medicines for Europe)	Director	Structure of antibiotic supply market, dependence on China, and views on reshoring policies
2023–06–13	International antibiotic development partnership	Director	Revenue guarantees for new antibiotic at global level (single countries contributions)
2023–06–12	Big pharma company, MAH	Market Access manager EU	Views on revenue guarantees and other policies to support antibiotic access
2023–06–12	Big pharma company, MAH	Medical affairs manager EU	Legal issues on policies to support antibiotic access
2023–02–24	Swedish Ministry of Health	Antibiotics policy lead	Transferability of Swedish policies to EU level
2023–02–24	Global non-profit antibiotic supplier (GARD-P SECURE)	Project Manager	Challenges to global access to antibiotics and potential solutions
2023–02–17	Swedish drug wholesaler	Managing director	Logistics activities, warehousing and inventories in Swedish supply chains.
2023–01–19	Swedish Ministry of Health	Antibiotics policy lead	Comparison Swedish barriers to access with EU-level barriers.
2023–01–11	Global non-profit antibiotic supplier (GARD-P SECURE)	Project Manager and academic advisor	Economic models for global purchasing in non-profit health providers
2022–12–16	Mid-sized pharma company, MAH	Medical advisor	Roles and contribution to multisectoral collaboration platform for access to antibiotics in Sweden
2022–05–31	Swedish medical reimbursement agency (TLV)	Chief analyst	Connection between sales levels, supply chain structure and deregistrations and shortages in Sweden
2022–05–30	Big pharma company, MAH	Sales Director Europe	Opinion about Swedish revenue guarantees for newer antibiotics
2022–05–18	Karolinska Institute	Health Economics professor	Assessment methods for costs of antibiotic shortages
2022–01–26	Swedish medical product agency (LV)	Department director	Policies to facilitate registration of old antibiotics already approved in other countries
2021–12–14	Consulting firm antibiotic manufacturing	Managing Director	Production technology and supply chains structures for antibiotics (main actors and bottlenecks)
2021–11–17	Big pharma company, MAH	Sales manager	Effects on competition of assigned Swedish revenue guarantees
2021–11–15	Mid-sized pharma company, MAH	Country manager	Effects on competition of assigned Swedish revenue guarantees
2021–11–09	Big pharma company, MAH	Policy officer	Opinion about Swedish revenue guarantees for newer antibiotics
2021–11–08	Big pharma company, MAH	Policy advisor	Effects on competition of assigned Swedish revenue guarantees
2021–10–25	Small pharma company, MAH	Sales manager	Opinion about Swedish revenue guarantees for newer antibiotics

Table A (continued)

Date	Organization or organization type	Interviewee	Topic
2021–10–27	Mid–sized pharma company, MAH	Head of market access	Opinion about Swedish revenue guarantees for newer antibiotics
2021–10–27	Mid-sized pharma company, MAH	Area manager Nordic	Effects on competition of assigned Swedish revenue guarantees
2021–10–22	Swedish pharmas association	Policy advisor	Pros and cons of Swedish revenue guarantees for newer antibiotics
2021–10–25	Swedish generics supplier association	Director	Pros and cons of Swedish revenue guarantees for newer antibiotics
2021–10–09	Contract manufacturer of antibiotics, FDF	Factory manager	Variation in key parameters of antibiotic supply chains: lead times, capacities, batch sizes, different production technologies
2021–10–07	Public Health Agency of Sweden	Department head	Quantitative indicators to forecast shortages and deregistrations of antibiotics
2021–09–15	Public Health Agency of Sweden	Project manager	Details and potential supplier reactions to new Swedish revenue guarantee model for newer antibiotics
2021–05–25	API and intermediate producer	Sustainability and public affairs director	Causes of antibiotic shortages, production processes and volumes of selected substances.
2021–03–08	Swedish medical product agency (LV)	Group leader	Solutions and responsibility for increasing transparency in drug supply chains.
2020–10–13	National Pharmaceutical Strategy Center	Director	Creating permanent collaboration platforms for antibiotic access and avoid shortages
2020–10–01	Swedish medical product agency (LV)	IT Manager	IT system and information flows to monitor drug supply chains in Sweden
2020–06–24	Pharmaceutical logistic consulting firm	Sustainable logistics expert	Structure of global supply chains, typical models.
2020–03–12	Swedish medical product agency (LV)	Regulatory officer	Key actors and elements in the agency's database of registered drugs' supply chains
2020–03–04	Contract manufacturer of antibiotics, FDF	Factory manager	Information flows with upstream suppliers, and IT solutions for production planning
2019–10–09	Contract manufacturer of antibiotics, FDF	Factory manager	Causes of antibiotic shortages from the perspective of final dosage formulation producer
2019–10–03	Swedish medical product agency (LV)	Group leader	Communication about drug shortages from suppliers and to the healthcare system
2019–06–18	Pharmaceutical logistic consulting firm	Sustainable logistics expert	Short and long-term supply risk, focus on specific antibiotics
2019–06–05	Contract manufacturer of antibiotics, FDF	Factory manager	Challenges and geographic risk in sourcing input materials (API) for drug formulation.

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