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How to Prevent Future Medicine Shortages

Insights and Recommendations in View of a Future EU Critical Medicines Act

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Shortages in the supply of various medicines have become a persistent phenomenon for many EU countries in recent years. Experience during the COVID-19 pandemic has demonstrated that combined supply and demand shocks can exacerbate existing supply chain issues to a threatening degree. This has led to calls to strengthen EU competence in risk monitoring and management beyond what has been implemented so far. Specifically, 19 Member States are calling for a Critical Medicines Act.

This cep**Input** provides a contribution to this debate. It develops proposals for an underlying monitoring methodology, examines current trade-related supply risks for selected commodities based on publicly available data, and provides a first insight into indirect network risks using the example of antibiotics.

Four short-term and two long-term measures are recommended to the EU and the Member States:

- ► Short-term: Develop a common framework for measuring trade-related risks.
- ► Short-term: Extend the toolbox and data availability for targeted risk diagnosis.
- ► Short-term: Evaluate the need for stockpiling on a product-specific cost-benefit basis.
- ► Short-term: Review and extend existing support channels for Research & Development spending.
- ► Long-term: Improve conditions for domestic cost competitiveness of medicine production.
- ► Long-term: Extend cooperation with reliable third countries.

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1 Policy Background and Aim of the Paper

1.1 Medicine Shortages as a Complex and Global Issue

In general, shortages of medicines have become increasingly common in recent years.[1] It is a complex global problem that has been receiving increasing attention.[2] Shortages of medicines seem to vary between countries in terms of, inter alia, number of shortages, therapeutic use and formulation of the medicines involved.[3] Yet, shortages have increased in many, if not most European countries since 2010.[4]

In this regard, one must acknowledge that especially poor data quality and major differences in the way shortages are reported make cross-country comparisons very challenging – even within an organisation such as the Organisation for Economic Co-operation and Development (OECD) for example.[5]

Yet, shortages of medicines represent a growing threat to public health. They have an impact on patient outcomes.[6] The root causes of shortages are multifactorial, including but not limited to supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components.[7] Generally, one can consider that shortages arise from either a rise in demand or a limitation of supply.[8]

The COVID-19 pandemic has exacerbated the situation of medicine shortages.[9] For example, antibiotics were in short supply in the USA.[10] This is why many countries are now pursuing policies aimed at improving the monitoring, mitigation, and prevention of future occurrences of shortages.[11] The EU response to the pandemic was manifold with a focus on supply vulnerabilities and "critical medicines".

1.2 The EU Response to COVID-19: Focus on Vulnerabilities and Critical Medicines

General Aspects

Generally, there is a significant need for coordination regarding both the preparations for and the response to cross-border health threats.[12] Yet, in the EU, this coordination has often been held back by a conflict of interests that should not be underestimated: on the one hand, the EU must be able to

1 See correspondingly for the OECD: Chapman, S.; Dedet, G.; Lopert, R. (2022), Shortages of medicines in OECD countries.
2 Chapman, S.; Dedet, G.; Lopert, R. (2022), Shortages of medicines in OECD countries, p. 48.
3 See Ravela, R.; Lyles, A.; Airaksinen, M. (2022), National and transnational drug shortages: a quantitative descriptive study of public registers in Europe and the USA, p. 10.
4 See Ravela, R.; Lyles, A.; Airaksinen, M. (2022), National and transnational drug shortages: a quantitative descriptive study of public registers in Europe and the USA, p. 2.
5 See correspondingly Chapman, S.; Dedet, G.; Lopert, R. (2022), Shortages of medicines in OECD countries, p. 4 and 19.
6 See Badreldin, H.; Atallah, B. (2020), Global drug shortages due to COVID-19: Impact on patient care and mitigation strategies, p. 1946 et seq.
7 See Commission Proposal for a Regulation laying down Union procedures for the authorisation and supervision of medicinal products use [COM(2023) 193], Recital 136 and Chapman, S.; Dedet, G.; Lopert, R. (2022), Shortages of medicines in OECD countries, p. 48.
8 Chapman, S.; Dedet, G.; Lopert, R. (2022), Shortages of medicines in OECD countries, p. 4. See also Section 2.3.
9 Chapman, S.; Dedet, G.; Lopert, R. (2022), Shortages of medicines in OECD countries, p. 4.
10 See Piatek, O.; Chien-min Ning, J.; Touchette, D. (2020), National drug shortages worsen during COVID-19 crisis: Proposal for a comprehensive model to monitor and address critical drug shortages, p. 1779.
11 Chapman, S.; Dedet, G.; Lopert, R. (2022), Shortages of medicines in OECD countries, p. 5.
12 cepInput 8/2022, p. 3.

react effectively to health crises; on the other, health policy[13] is fundamentally a matter for the Member States.[14]

Especially the early phase of the pandemic showed that the EU was not sufficiently equipped to face cross-border health threats such as COVID-19 due to the lack of an adequate legal framework for prevention and problem-solving capacities. The EU was under heavy criticism and some even saw the pandemic as a major challenge to the survival of the EU.[15]

First Reactions, the "European Health Union" and HERA

Without a suitable legal framework in place, ad-hoc solutions were found at EU level to mitigate the risk of shortages of then crucial products, such as ventilators, surgical masks and test kits.[16] After these initial measures were completed, the EU began to build new structures and propose legal changes to enhance its prevention and problem-solving capacities.

In September 2021, under the political umbrella term "European Health Union"[17], the Commission created the European Health Emergency Preparedness and Response Authority (HERA) as a so-called Commission Service[18].[19]

HERA aims to strengthen health security coordination within the EU during preparedness and crisis response times and to address vulnerabilities and strategic dependencies related to the development, production, procurement, stockpiling and distribution of "medical countermeasures",[20] i.e. medicines, medical devices and other goods or services that are necessary for the purpose of preparedness for and response to serious cross-border threats to health,[21] such as vaccines, medicines and medical equipment.[22] Thus, HERA will undertake the strategic assessment of health threats, promote research and development in that regard, and procure and distribute essential medical supplies.[23] In short: it needs to ensure Member States have rapid and equal access to key medical products in the event of an emergency.[24]

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13 On the division of competences see cep**Input** 4/2021, p. 3-6.

14 In practice, this conflict became apparent in various situations – we refer by way of example to COVID-19 and the Council Recommendation of 25 January 2022 in which it was agreed that a person was deemed to be "recovered" six months after a confirmed infection – see No. 12 (c) of Recommendation (EU) 2022/107 – shortly before this, the corresponding time interval had been lowered in Germany to three months; see RKI (2022), Fachliche Vorgaben für Genesenennachweise (mit Wirkung vom 15.01.2022).

15 See e.g. aerzteblatt.de (2020), Coronapandemie: Bewährungsprobe für Europa. Whereas others have said that successful pandemic control may also strengthen European integration, see Häberle/Kotzur, Die COVID-19-Pandemie aus der kulturwissenschaftlichen Perspektive einer europäischen und universalen Verfassungslehre, in: NJW 2021, p. 135.

16 See altogether cep**PolicyBrief** 12/2021, p. 1.

17 See generally on this cep**Input** 4/2021.

18 Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority (HERA).

19 The establishing of a new independent agency, like the EMA or ECDC, would have been much more complicated and time-consuming as it would have required several agreements among the Member States that are not easy to reach, e.g., on the location of the head office of the agency; see cep**Input** 8/2022, p. 4 et seq.

20 Art. 2 (1) Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority (HERA).

21 Art. 3 (10) Regulation on serious cross-border threats to health [(EU) 2022/2371].

22 See Recital 6 Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority (HERA).

23 Art. 2 (1) and (2) Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority (HERA).

24 cep**Input** 8/2022, p. 3.

EMA, the MSSG and "Critical Medicines" in Times of Emergency

Furthermore, in 2022, the EU enacted legislation which has given new competences to both the European Centre for Disease Prevention and Control (ECDC)[25] as well as the European Medicines Agency (EMA)[26] to be able to provide a more coordinated and faster response before and during a public health crisis at EU level.

This legislation can best be described as "crisis mode" legislation as the mechanisms come into play in the event of an emergency, i.e. when certain cross-border health threats materialise. In legal terms, on the occurrence of a "major event"[27] or a "public health emergency at Union level"[28].

Within EMA, the "Medicine Shortages Steering Group" (MSSG) – consisting of one representative from EMA, one from the Commission and one from each Member State – was established.[29] One of its tasks is to identify and list "critical medicines" which are considered to be crucial during times of emergency.[30] Such a list was adopted with regard to COVID-19 in June 2022, which became obsolete once that emergency situation was over.[31]

"Critical Medicines" in the Pharmaceutical Legislation Reform

In April 2023, the Commission suggested proposals for a substantial reform of the current EU general pharmaceutical legislation (hereinafter "the Reform"). It aims[32] to repeal today's core pharmaceutical legislation, adapt and update its regulations and merge those into two new comprehensive laws.[33]

With the Reform, the Commission aims to further mitigate the risk of shortages by establishing structures and mechanisms outside a "crisis mode" as a sort of permanent precautionary mechanism, especially by introducing new obligations, inter alia, on pharmaceutical companies to notify shortages and withdrawals of medicines.[34]

The Reform also entails new procedures to ensure a continued supply of "critical medicines". In the Commission proposals, a medicine is considered to be "critical" if insufficient supply of it results in serious harm or risk of serious harm to patients and it has been identified as a "critical medicine" at

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25 On the corresponding Commission proposal see cep**PolicyBrief** 17/2021.
26 On the corresponding Commission proposal see cep**PolicyBrief** 12/2021.
27 See Art. 2 (b), Art. 4 (1), (3) and (4) Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices [(EU) 2022/123].
28 See Art. 23 et seq. Regulation on serious cross-border threats to health [(EU) 2022/2371].
29 Art. 3 (1) and (2) Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices [(EU) 2022/123].
30 Art. 6 (2) and (3) Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices [(EU) 2022/123].
31 See https://www.ema.europa.eu/en/documents/other/list-critical-medicines-covid-19-public-health-emergency-phe-under-regulation-eu-2022/123-obsolete_en.pdf.
32 The legislative procedures are still at a very early stage and adoption is not to be expected any time soon.
33 That is (1) a Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency [COM(2023) 193, hereinafter "Regulation Proposal"] and (2) a Directive on the Union code relating to medicinal products for human use [COM(2023) 192, hereinafter "Directive Proposal"].
34 Regulation Proposal, p. 1 et seq.

EU level.[35] Identification and management of critical medicines at EU level are to be handled by the Member States, the EMA, the MSSG as well as the Commission.[36]

For this, the EMA must develop a common methodology to identify critical medicines including the evaluation of vulnerabilities with respect to the relevant supply chains.[37] The Member States must – based on the yet to be created common methodology – identify critical medicines in their country and report these to the EMA.[38] A "Union list of critical medicinal products" (hereinafter "EU list of critical medicines") is then prepared and proposed by EMA and MSSG and adopted by the Commission via an implementing act.[39]

1.3 Further Calls for a Strategic Long-Term EU Approach to Critical Medicines

A "Non-paper" of 19 Member States

In May 2023, 19 Member States[40] agreed to a "Non-paper" on improving the security of medicines supply in Europe (hereinafter "Non-paper" or "Non-paper on security of medicines supply").[41] In it, these Member States emphasise that the EU has been confronted with severe medicines shortages and that essential medicines, such as antibiotics, were particularly difficult to obtain.[42]

In addition, they reiterate that the EU is becoming increasingly dependent on imports from a few manufacturers and a few regions. These Member States welcome the work of the MSSG as well as the Reform, but they are of the opinion that the EU must take more drastic steps to improve the security of medicines supply[43] – complementary to the initiatives already taken (EMA & MSSG) or announced (the Reform).[44]

A "Critical Medicines Act": The Commission Under Pressure to Move

For this, the Non-paper proposes different points of action. Among them, the suggestion of exploring a "Critical Medicines Act" to reduce dependencies for critical medicines and ingredients, particularly for products were there are only a few supplying manufacturers or countries.[45]

The concerned Member States want to follow the example of the European Chips Act[46] and the Critical Raw Materials Act[47] and ask the Commission to present a proposal for a Critical Medicines Act which supports the "European green, digital manufacturing of key medicines, [active pharmaceutical

35 Art. 2 (13) Regulation Proposal, Art. 127 Regulation proposal.
36 Art. 127, Art. 130-132, Art. 134 Regulation Proposal.
37 Art. 130 (1) (a) Regulation Proposal.
38 Art. 127 (1) and (2) Regulation Proposal.
39 Art. 130 (1) (b), Art. 131 (1) and (3) Regulation Proposal.
40 Belgium, Austria, the Netherlands, Luxembourg, Hungary, Czechia, Spain, France, Germany, Estonia, Slovenia, Romania, Latvia, Lithuania, Greece, Malta, Poland, Italy and Portugal.
41 See https://www.politico.eu/wp-content/uploads/2023/05/02/Non-paper-security-of-medicines-supply-02.05.23.pdf.
42 Non-paper on security of medicines supply, p. 1.
43 Non-paper on security of medicines supply, p. 1.
44 Non-paper on security of medicines supply, p. 2.
45 Non-paper on security of medicines supply, p. 2.
46 See cep**PolicyBrief** 8/2022.
47 See cep**PolicyBrief** 8/2023.

ingredients] and intermediate ingredients" for which the EU is entirely dependent on one country or a limited number of manufacturers.[48]

Only the Commission has the legal right to propose new legislation and initiate a legislative procedure.[49] So it is in the Commission's discretion to submit a proposal to Parliament and the Council. Yet, the Commission is now under huge political pressure to act. Firstly, because the severe shortages have been recognised by the public at large. Secondly, the signatory countries to the Non-paper make up 70 % of the Member States and 90 % of the EU population – far beyond the necessary requirements for a qualified-majority decision in the Council.[50]

1.4 Aim: A Framework for Critical Medicines

The aspects connected with the issue of "critical medicines" – in the sense of avoiding shortages of certain essential medicines for public health by various means – go beyond the healthcare sector in the narrower sense. The multifactorial nature of this issue makes it difficult to understand.[51] Generally, no one country is able to produce all the necessary components and medicines for its population[52], all are in fact reliant on other countries.[53] Consequently, measuring international trade flows can offer some insights into the extent of the interdependencies,[54] more precisely in this case: EU dependencies.

It has been shown that the lack of comparable data makes any root cause analysis difficult.[55] In order to make a partial contribution to the work on critical medicines, this paper will develop an initial approach to developing an underlying methodology for identifying supply risks based on publicly available trade data.

Generally, one has to look at the product level, meaning a medicine as a whole (hereinafter "medicinal product"), as well as the ingredient level, with the "active pharmaceutical ingredients" (API)[56] generally constituting the key ingredients. Altogether, this analysis will be exemplified by a sample group of antibiotics, as antibiotics occupy a special position with regard to public health and have been highlighted by the concerned Member States in the Non-paper.[57]

To begin with, in this cep**Input**, first concepts and recommendations will be developed to make supply risks measurable (Chapter 2). This is followed by a network analysis of trade networks with regard to the sample group of antibiotics on the basis of publicly available trade data (Chapter 3). The empirical findings will be used to derive recommendations for the work on "critical medicines" at EU level, especially with a view to a possible Critical Medicines Act (Chapter 4).

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48 Non-paper on security of medicines supply, p. 3.
49 Art. 289 and Art. 294 Treaty on the Functioning of the European Union (TFEU).
50 Art. 16 Treaty on European Union (TEU) and Art. 238 (2) TFEU.
51 See correspondingly with regard to shortages of medicines: Chapman, S.; Dedet, G.; Lopert, R. (2022), Shortages of medicines in OECD countries, p. 4.
52 Chapman, S.; Dedet, G.; Lopert, R. (2022), Shortages of medicines in OECD countries, p. 29.
53 Chapman, S.; Dedet, G.; Lopert, R. (2022), Shortages of medicines in OECD countries, p. 29.
54 See generally also Chapman, S.; Dedet, G.; Lopert, R. (2022), Shortages of medicines in OECD countries, p. 29.
55 See generally also Chapman, S.; Dedet, G.; Lopert, R. (2022), Shortages of medicines in OECD countries, p. 4.
56 That is substances in a medicine which are intended to have a direct effect in the diagnosis, cure, mitigation, treatment, or prevention of a disease or which affect the structure and function of the body; see accordingly, EudraGMDP Glossary. The EudraGMDP database is the EU database on manufacturing, import and wholesale-distribution authorisations, and good manufacturing-practice (GMP) and good-distribution-practice (GDP) certificates; see EMA, Human Regulatory.
57 Generally, see cep**Input** 2/2023. Specifically, to critical medicines, see the fact that antibiotics are especially highlighted in the Non-paper on security of medicines supply.

2 Measuring Shortage Risks for Medicines

2.1 Overview on Risk-determining Factors

The diversity and complexity of the manufacture of medicinal products pose a major challenge for comprehensive risk management. Strong forces on the demand side, triggered by changes in treatment methods, ensure constant pressure to adapt on the supply side. The strict regulatory requirements for production and trade, which differ from country to country, represent another important factor influencing the market, complicating the economic distribution process, and rendering forecasts on the future development of shortage risks extremely difficult.

When identifying risk factors, a distinction can first be made between global and local factors. **Global risk factors relate to the established structure of international supply chains of medicinal products, in particular the combination of vertical spatial fragmentation and horizontal spatial concentration**.[58] Vertical fragmentation refers to the fact that the production process of medicinal products is broken down into a multitude of individual process steps in which different companies and countries specialize. This generates high organizational costs and makes supply chains particularly vulnerable to supply failure at individual stages. Horizontal concentration refers to the concentration of specific process steps in individual companies and countries. This creates strong dependencies, which in turn increase the probability of supply disruptions in individual steps.

At the local level, external dependency in supply, e.g. caused by the relocation of domestic production abroad, can represent a risk factor if supply rests on countries characterized by high regulatory uncertainty or high risk of political instability. Moreover, apart from the political side, importers are exposed to risks of technical disruptions in the supply chain resulting e.g. from logistical problems or unforeseeable shock events such as natural disasters and pandemics. These risks are often not independent but tend to accumulate, which is a potential cause of long-lasting multi-factor crises. The recent chips shortage crisis is a prominent example for this.[59]

Current figures suggest that such external dependence threatens to become a reality for EU medicine supply in the future. While the EU is currently still a net exporter of pharmaceuticals, and exhibits evident comparative advantage for these products[60], indicators point to an overall deterioration in the market position in recent years, particularly for APIs. For instance, an analysis by the industry association *progenerika* of the distribution of valid Certificates of Suitability of Monographs of the European Pharmacopoeia (CEPs), proof of the quality of active pharmaceutical ingredients and used for drug approvals in the EU, showed that in the year 2020 two-thirds of CEPs were held by Asian manufacturers. Between the years 2000 and 2020, Asian manufacturers have increased the number of their CEPs from 183 to 2369, European manufacturers only from 348 to 1260.[61]

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58 European Commission (2021), Future-proofing pharmaceutical legislation —study on medicine shortages. Final Report. Study by Technopolis Group, Ecorys BV, Milieu Law & Policy Consulting for the European Commission. December 2021.

59 Wu, X.; Zhang, C.; Du, W. (2021), An analysis on the crisis of "chips shortage" in automobile industry——Based on the double influence of COVID-19 and trade Friction. Journal of Physics: Conference Series (Vol. 1971, No. 1, p. 012100). IOP Publishing.

60 Erixon, F.; Guinea, O. (2023), Strategic Autonomy and the Competitiveness of Europe's Innovative Pharmaceutical Sector: A Wake-up Call. European Center for International Political Economy. Policy Brief No.5/2023.

61 progenerika (2020), Where do our active pharmaceutical ingredients come from? A world map of API production. Final Report, September 2020.

Warning signs of a future loss of competitiveness are also evident in innovation activity. In the field of R&D spending, European manufacturers have been eclipsed by the USA in the last two decades. While the annual R&D expenditures of pharmaceutical companies tripled in the USA between 2000 and 2020, they only doubled in the EU and Switzerland.[62] The latest developments are particularly worrying. For example, the number of new chemical and biological entities recently declined in a five-year comparison (2017-2021 vs. 2012-2016) in Europe, while almost doubling in the US over the same period.[63]

The reasons for this loss of market position primarily arise from a lack of profitability prospects. While Europe has traditionally been at a cost disadvantage compared with other regions regarding labour costs, higher energy costs have recently become an added drawback.[64] The high intensity of legislative regulation also has a dampening effect, and in more ways than one. On the one hand, its complexity creates considerable compliance costs for companies, and on the other, the tightness of price regulation limits the possibilities for flexible cost transfer.[65] Especially from the perspective of innovative pharmaceutical start-ups, the lack of sufficient access to venture capital in EU countries also represents an obstacle.[66]

Before analysing the consequences of these trends and taking appropriate countermeasures, it is essential for the EU to obtain an overview of the resulting risks. A range of studies have been published on this subject in recent years. In the following, we attempt to classify the risk factors in terms of their role and thus to create a structure for overarching risk monitoring.

2.2 Existing Approaches to Risk Measurement

The first question in the development of a risk monitoring methodology for the medical sector is which possible role models can be used. The methodology for risk monitoring of mineral resources developed by the Commission in recent years[67] and currently expanded in the context of the legislative process for the Critical Raw Materials Act[68] offers an example. For these resources, the Commission has established a system of transparent indicators used for a quantitative assessment of criticality based on the pillars of economic importance and shortage risk. However, direct transferability of this methodology to the medical field cannot be recommended due to some essential differences.

This begins with the more fundamental social significance of criticality in the medical field. In this case, the primary objective should not be to safeguard the competitiveness of domestic industry, but to ensure that the population has access to high-quality medicine. The economic importance of individual products measured in terms of value added is therefore unsuitable as an indicator. Instead, importance should be assessed from a medical perspective.

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62 See Erixson & Guinea (2023).
63 See Erixson & Guinea (2023).
64 Grover, N. (2022). Energy crisis risks upending Europe's key medicine supply chains - industry says. Reuters. October 27, 2022.
65 Martuscelli, C. (2023), The real reason Europe's medicines industry is dying. Politico, April 25 2023.
66 Küsters, A.; Meister, A.; Poli, E; Warhem, V.; Wolf, A. (2023), Catalyzing the EU's Green Industrial Transformation—A Survey of the Cleantech Startups Environment in Germany, France, and Italy. CepInput Nr. 05/2023.
67 European Commission (2023), Study on the Critical Raw Materials for the EU 2023. Final Report.
68 European Commission (2023), Proposal for a regulation of the European Parliament and the Council establishing a framework for ensuring a secure and sustainable supply of criti-cal raw materials and amending Regulations (EU) 168/2013, (EU) 2018/858, 2018/1724 and (EU) 2019/1020 (COM(2023) 160 final).

A range of factors complicate the criticality assessment. The first factor is that – unlike in the case of mineral raw materials – not only the first steps of the supply chain need to be considered, but in principle the entire processing route - starting with the production of basic chemicals and ending with the supply of finished medicinal products. This is because the decisive factor for criticality is the supply of the finished product, which can in principle be affected by influences along the entire supply chain. Another specific feature is the great variety of relevant products and the complexity of their manufacturing routes. This renders supply chain monitoring a particularly challenging task that necessarily requires a high degree of prioritization and abstraction. Another relevant feature is the rapid technological progress, expressed in the development of new APIs and finished products. This complicates the medium-term assessment of the availability of substitutes as a key indicator in the criticality assessment. Demand-side dynamics are also significant, whether in the form of permanent (due to new treatments or changed needs) or temporary (in times of health crises) adjustments. Taking into account the uncertainty of demand trends and short-term shock events further increases the complexity of criticality analyses and requires extensive scenario modelling.

A fundamental challenge for indicator-based assessment of current supply chains is limited data availability. While there are recognized global comparative indicators for critical mineral raw materials, a comprehensive public investigation of worldwide supply chains in the medical sector must essentially rely on data from foreign trade statistics. Although this provides a timely picture of possible shifts, its information content is restricted due to the limited disaggregation and the peculiarities of its product classification systems. **This makes it especially important to exploit the potential of the data in the best way possible by applying up-to-date scientific methodology** (see our example analysis in Chapter 3).

In a Staff Working Document from 2022, the Commission outlined the main features of a Draft Methodology for the identification of critical medicines. It was developed in the context of a "Structured Dialogue on the Security of Medicines Supply" together with various stakeholders in the European healthcare system. It consists of a medical evaluation of the product regarding 1) its therapeutic indication and 2) the availability of adequate alternatives. Both indicators are to be classified on a three-level scale (high/medium/low risk), which together form a risk matrix. The medicines classified as risky on this basis are declared "medicines at risk". The consideration of supply-chain related risks only takes place in a subordinate form. Corresponding supply chain analyses are only carried out for those groups of products that have previously been classified as "medicines at risk". If high vulnerability of supply is diagnosed, the product in question is additionally classified as a "critical medicine".[69]

The Staff Working Document does not yet provide any concrete methodological guidelines for the assessment of supply chain vulnerability. Existing classification approaches at the national level (e.g. in Germany the “List of APIs relevant to supply”[70]) so far also exclusively focus on medical criteria. In the following, we would like to make some of our own suggestions for the structuring of a supply-chain related risk classification system and illustrate its possibilities and limitations based on public data.

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69 European Commission (2022), Vulnerabilities of the global supply chains of medicines - Structured Dialogue on the security of medicines supply. Commission Staff Working Document.

70 BfARM (2023). Liste der versorgungsrelevanten Wirkstoffe nach § 52b Absatz 3c AMG. Bundesinstitut für Arzneimittel und Medizinprodukte.

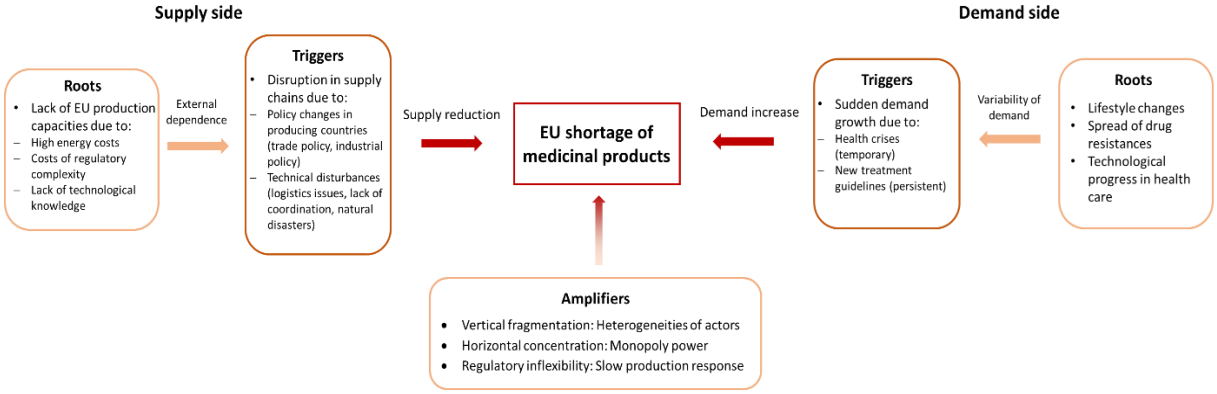
2.3 Proposal for a Classification of Supply-chain-related Risks

Previous approaches to identifying supply-chain-related risks for medicinal products essentially consist of a one-dimensional list of different risk factors. The likely hierarchy in their chain of effects is not made explicit. This is an issue for the development of suitable risk management instruments. For instance, instruments that primarily respond to the triggers of potential supply crises could have a less lasting effect on supply security than those that address the roots of a shortage risk. Ideally, the latter would reduce the probability of threat scenarios occurring – instead of merely the expected damage when they do occur.

From an EU perspective, such a distinction requires a closer look at the interplay of risks. In the following, we propose a rough subdivision of risk factors into the following classes: roots, triggers, and amplifiers. By "roots" we mean the root causes of a shortage situation for certain APIs or finished medicinal products from an EU perspective. These can be situated on the supply side as well as on the demand side. By "triggers" we mean the direct triggers of shortage situations, likewise differentiated into supply-side and demand-side triggers. These are located further downstream in the chain of effects. Finally, by "amplifiers" we mean risk factors that exacerbate shortage situations when they do occur.

Figure 1 illustrates our risk classification with a selection of specific risk factors from the EU perspective. An important root on the supply side is the mostly cost-driven (and in some cases knowledge-driven) loss of domestic production capacities, which creates external dependencies for the EU on the production side. Specific triggers are disruptions to existing external supply relationships, whether they are political or technical in nature. Shortage situations can also be triggered by unexpected increases in demand for certain medicinal products. The underlying demand-side causes, in turn, are of a health-related and a social nature. A potential amplifier is the structure of international supply chains. If supply chains are characterized by a strong horizontal concentration of production capacities on individual players (see Section 2.2), there are few possibilities of falling back on other suppliers in the event of supply disruptions. Another amplifier is vertical fragmentation, which makes coordination more difficult in the event of capacity bottlenecks. Moreover, domestic regulatory requirements can act as an amplifier if they hinder a rapid buildup/reactivation of domestic production capacity in shortage situations. The relevance of all these factors and their interactions are, of course, highly time- and product-specific.

Figure 1: Proposed classification scheme for supply-chain-related risks



Source: own illustration.

The classification scheme developed offers the possibility of evaluating regulatory instruments in terms of their effectiveness, although fundamental trade-offs must be taken into account. For example, approaches that address the roots instead of the triggers of shortage situations may have a more sustainable impact. However, they will typically also involve more fundamental interventions in the established supply structure, which can entail significant social costs (e.g., efficiency losses, higher prices, and/or additional government spending). In Chapter 4, we evaluate in more detail the potentials and limitations of individual instruments against this background.

2.4 Risk Analysis for Selected Product Categories

To be applicable to practical risk management and critical drug selection, the risk classification developed in the previous section must be operationalized by measurable indicators. Ideally, such indicators should be measured at the level of specific products. However, the market analyses required for this purpose have so far generally not been available in the form of publicly accessible data sets, but only as commercial services. Basic requirements for data collection, such as transparency and comparability, are thus hardly met. As long as no specific surveys by public agencies exist, recourse to public indicators at a higher level of aggregation - combined with the results of qualitative expert assessments - is a sensible alternative approach.

In the following, we conduct an example risk analysis for Europe's current procurement situation based on such publicly available indicators. To this end, we combine current data on trade patterns for APIs and finished medicinal products with macro indicators on production in the EU and the country risks of EU trading partners. Table 1 provides an overview of how each indicator is measured and its data basis. To implement the data from trade statistics, we need to base our analysis on the Harmonized System (HS), the official goods classification of trade statistics that divides trade in commodities into about 5000 commodity groups. For the example analysis in this section, we consider aggregates based on the "headings" (four-digit level) and "subheadings" (six-digit level) aggregation level of the HS classification. We compare a total of nine different product groups (five classes of APIs, four classes of finished medicinal products).

Table 1: Overview of direct supply risk indicators

Indicator	Measure	Calculation	Data Sources
Aggegate Import Dependence	Share of domestic needs sourced from external supply (0-1)	(Imports - Exports) / (Domestic Production + Imports - Exports)	UN Comtrade[71]; Eurostat PRODCOM[72]
HHI-Index EU-Imports	Supplier concentration in EU imports	Sum of squared import shares of single supplier countries	UN Comtrade
Political Stability External Suppliers	Average level of political stability of supplier countries	Weighted average of WGI-Indicator "Political Stability" of supplier countries (weights: import values)	UN Comtrade, Worldwide Governance Indicators[73]
Regulatory Quality External Suppliers	Average level of regulatory quality of supplier countries	Weighted average of WGI-Indicator "Regulatory Quality" of supplier countries (weights: import values)	UN Comtrade, Worldwide Governance Indicators

Source: Own representation

71 UN Comtrade (2023), UN Comtrade Database. United Nations, New York.
72 Eurostat (2023), PRODCOM database.
73 World Bank (2023), Worldwide Governance Indicators. World Bank, Washington D.C.

The first basic indicator is used to identify and measure the EU's degree of import dependence for the respective product group. Import dependence basically measures the proportion of the EU's internal consumption that is satisfied by imports (rather than domestic sources). Although information on the level of internal EU consumption of certain pharmaceuticals is available from various EU surveys, it is only reported in the form of "daily doses".[74] Thus, this information does not coincide with the units of trade statistics (weight (tons) and trade value (currency)). For this reason, we propose the indirect approach for measuring apparent consumption, as is already practiced for critical raw materials. In this approach, consumption is measured indirectly from existing information on export, import and domestic production values.[75]

This basic indicator is supplemented by assessments of origin-specific risks for imported products. Politically induced risks can take the form of regulatory uncertainty regarding the future trade policy (risk of export restrictions) or industrial policy (changes to regulatory production incentives) of the exporting country. This form of uncertainty is not directly measurable, given the diversity of potential policy instruments. However, as part of its Worldwide Governance Indicators (WGI), the World Bank regularly publishes expert assessments of the general confidence in the regulatory systems of countries worldwide in the form of the country indicator "Regulatory Quality". A more fundamental form of political risk is posed by potential supply disruptions resulting from periods of political instability in the countries of origin. The WGI indicator "Political Stability and Absence of Violence" provides expert assessments of the relative extent of this risk. Finally, the extent of supply concentration as an amplifying risk factor can be calculated using the classic Herfindahl-Hirschman index applied to the supply shares of individual trading partners in EU imports.

In the trade in the product groups considered, the EU was consistently a net exporter in 2021, except for antibiotic active ingredients (see Table 2). However, figures for total trade per group fail to reveal the considerable heterogeneity among APIs at the level of the associated subgroups. For example, the EU was a net importer for six of eleven subgroups of vitamin active ingredients in the trade statistics. The EU trade balance was also negative for some hormone and alkaloid active ingredients. For finished drug products, on the other hand, the EU was consistently a net exporter, even in the maximum available product resolution. Overall, import dependence thus appears stronger for active ingredients, and in particular antibiotics, where the EU was clearly a net importer for all six subgroups.

Systematic differences are also evident in the origin of imports. For finished medicinal products, Switzerland, the USA, and the United Kingdom were by far the most important trading partners overall. The assessments of political stability and regulatory quality are correspondingly positive. They are also significantly above the average values for EU goods imports overall. In the case of active ingredients, China and India play a more important role as emerging markets. For example, China was by far the EU's most important supplier of vitamins and alkaloids. Consequently, the assessment of regulatory quality is less favourable in these segments. Similar heterogeneity is also evident in the geographical concentration of the countries of origin.

74 ECDC (2022), Antimicrobial consumption in the EU/EEA (ESAC-Net), Annual Epidemiological Report for 2021.
75 European Commission (2023), Study on the Critical Raw Materials for the EU 2023. Final Report.

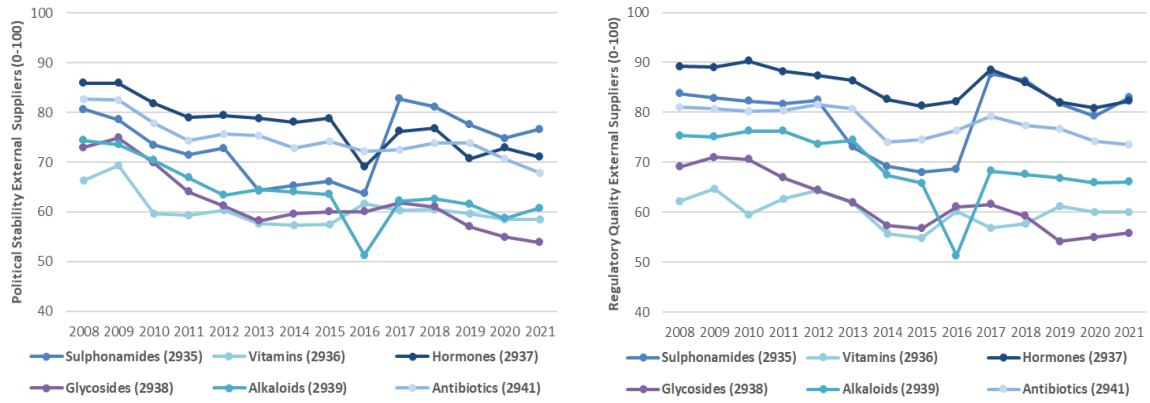
Table 2: Overview of EU supply risk indicators for different APIs and finished medicinal products

		APIs				
Products	**HS Code(s)**	**2935**	**2936**	**2937**	**2938/2939**	**2941**
	Name	**Sulphonamides**	**Provitamins, vitamins**	**Hormones, prostaglandins, thromboxanes and leukotrienes**	**Glycosides / Alkaloids**	**Antibiotics**
Aggregate import dependence		0	0	0	0	0,37
Number of subcategories with EU as net importer		1 of 6	6 of 11	4 of 9	6 of 16	6 of 6
HHI-Index EU-Imports (0-1)		0.45	0.38	0.39	0.24	0.30
Political stability external suppliers (0-100)		76.59	58.47	71.06	57.52	67.75
Regulatory quality external suppliers (0-100)		82.95	60.11	82.29	61.27	73.58
Top 3 External Suppliers	1	Switzerland (64%)	China (57%)	Switzerland (50%)	China (38%)	Switzerland (42%)
(in value terms)	2	India (7%)	Switzerland (20%)	USA (36%)	India (15%)	China (27%)
	3	Singapore (7%)	UK (9%)	China (6%)	Switzerland (13%)	USA (16%)
Products		**Finished medicinal products**				**Total merchandise imports EU**
	HS Code(s)	**300410/300420**	**300431/300432/300439**	**300441/300442/300443/300449**	**300450**	**All**
	Name	**Medicaments; containing antibiotics (p.r.s)**	**Medicaments; containing hormones (p.r.s)**	**Medicaments; containing alkaloids (p.r.s)**	**Medicaments; containing vitamins (p.r.s)**	**All products**
Aggregate import dependence		0	0	0	0	-
Number of subcategories with EU as net importer		0 of 2	0 of 3	0 of 4	0 of 1	-
HHI-Index EU-Imports (0-1)		0.25	0.28	0.40	0.22	0.09
Political stability external suppliers (0-100)		68.93	73.63	69.05	73.37	55.16
Regulatory quality external suppliers (0-100)		79.91	85.11	83.34	86.33	48.88
Top 3 External Suppliers	1	Switzerland (32%)	Switzerland (37%)	Utd. Kingd. (60%)	Norway (37%)	
(in value terms)	2	USA (32%)	USA (17%)	Switzerland (16%)	Switzerland (22%)	
	3	Utd. Kingd. (13%)	UK (14%)	India (7%)	Utd. Kingd. (12%)	

Source: own calculations.

In addition, a look at the evolution of risk indicators provides information on potential trends in EU risk exposure over time. Figure 2 displays the evolution of two of the supply risk indicators from the above table for the different classes of APIs. **Accordingly, risk measurements have not systematically improved for any of these product groups in recent years. Quite the opposite, at least for antibiotics, hormones and glycosides, a clear downward trend in both the regulatory quality and political stability of external suppliers can be diagnosed.** At the same time, short-term volatility in these measurements is revealed to be highly product-specific, further supporting the need for a disaggregated analysis.

Figure 2: Evolution of EU supply risk indicators for different APIs over time



Source: own calculations.

A more in-depth risk analysis requires a look at the dependencies arising from the connections in supply chains and trade networks. A full supply chain view would have to include the origin of base chemicals used to produce APIs. However, the complexity of supply chains caused by the diversity of materials and substitution possibilities exceeds the capabilities of an overarching public risk monitoring.

Another source of indirect risks is the intermediate trade in APIs or unfinished pharmaceutical products. The availability of products from countries that act as intermediaries in the international supply network depends on a wide set of risks on the part of their suppliers. Although pure transit trade is not included in international trade statistics by default, minor forms of processing are sufficient to record the intermediary country as an exporter. An example of risk patterns masked by this is the trade in erythromycin/erythromycin derivatives (HS code 294150). In addition to China, India and the United States were major suppliers to the EU in this class of antibiotics in 2021. However, both countries in turn reported significant erythromycin imports from China. Thus, the importance of China for the EU's security of supply of erythromycin tends to be underestimated if only direct relationships are scrutinized. Methodologically, an assessment of such indirect risks requires the investigation of network structures in global trade. Established methods of network analysis can provide assistance. In the following section, we apply such methods to the example case of trade in antibiotics.

3 Risks Embedded in Global Antibiotics Trade: a Network Analysis

3.1 Method and Data

To map the dependencies and risks in the international trade networks of antibiotics, we resort to the tool of network analysis. The field of network analysis comprises established methods for analysing complex webs of relationships. These can include social relationships between individuals and groups, but also forms of economic interaction. Networks are usually presented graphically and their (global and local) properties are summarized in the form of indicators. The basic building blocks of any network analysis are the individuals under consideration (so-called *nodes*) and their bilateral connections (so-called *edges*). The individual connections can be weighted for the analysis. Thus, in addition to the existence, the intensity of the bilateral relationships can also be taken into account by the analysis.

Risk indicators can also serve as weighting factors. On this basis, analyses can be carried out to determine the extent of indirect risks for specific nodes resulting from the network structure.

In the following, we examine the trade network for different product segments of antibiotics. **The choice of antibiotics is motivated not only by their broad medical field of application, but also by Europe's strong dependence on imports, as diagnosed in the previous section. It makes identifying indirect sourcing risks - in addition to the direct risks already discussed - particularly important.** Specifically, we look at reported import and export relationships in antibiotics between all countries worldwide for two observation years: 2001 and 2021. This comparison allows us to detect long-term trends in trade patterns and their risk implications. Bilateral trade volumes and country-specific risk indicators are used as weights. The direction of trade flows is also considered. Technically, it is thus a weighted and directed network.

In order for the trade connections to be interpreted as a trade network, the traded good should be defined as narrowly as possible. The maximum disaggregation in the Harmonized System (HS), the underlying commodity classification of international trade statistics, is the six-digit level. Antibiotic active ingredients (super-group: 2941) are divided into six different classes of active ingredients at this level: Penicillin (294110), Streptomycin (2941120), Tetracycline (294130), Chloramphenicol (294140), Erythromycin (294150), Other Antibiotics (294190). In addition to these basic APIs, trade in their derivatives is also included (e.g., phenoxymethylpenicillin in the case of penicillin).

In the following, we take a differentiated look at the trade networks of the first five active antibiotics classes (204110-50). They account together for about 60 % of EU imports of antibiotics in 2021 in weight terms. When interpreting the data, it should be borne in mind that the networks under consideration may also include additional processing (production of derivatives based on basic active ingredients). We use the bilateral trade flows recorded in the UN Comtrade Database as the basis for our data. Since import statistics are generally more precise than export statistics, we use the import values (CIF) recorded by the reporting countries as weighting factors. We compare the covered networks based on established network indicators, both with each other and over time. We start with the global properties of the network. We then look at country-specific properties and their size distribution. Finally, we perform a risk analysis. For this purpose, we propose a simple and intuitive indicator for the extent of regulatory risk (based on the WGI indicator "Regulatory Quality" from Section 2.4), which we implement as a weighting factor in the network. In doing so, to focus on EU-external risks, we treat the EU27 countries as one trade node, i.e. we do not consider Intra-EU trade, but analyse trade relations of the EU27 as a whole with third countries.

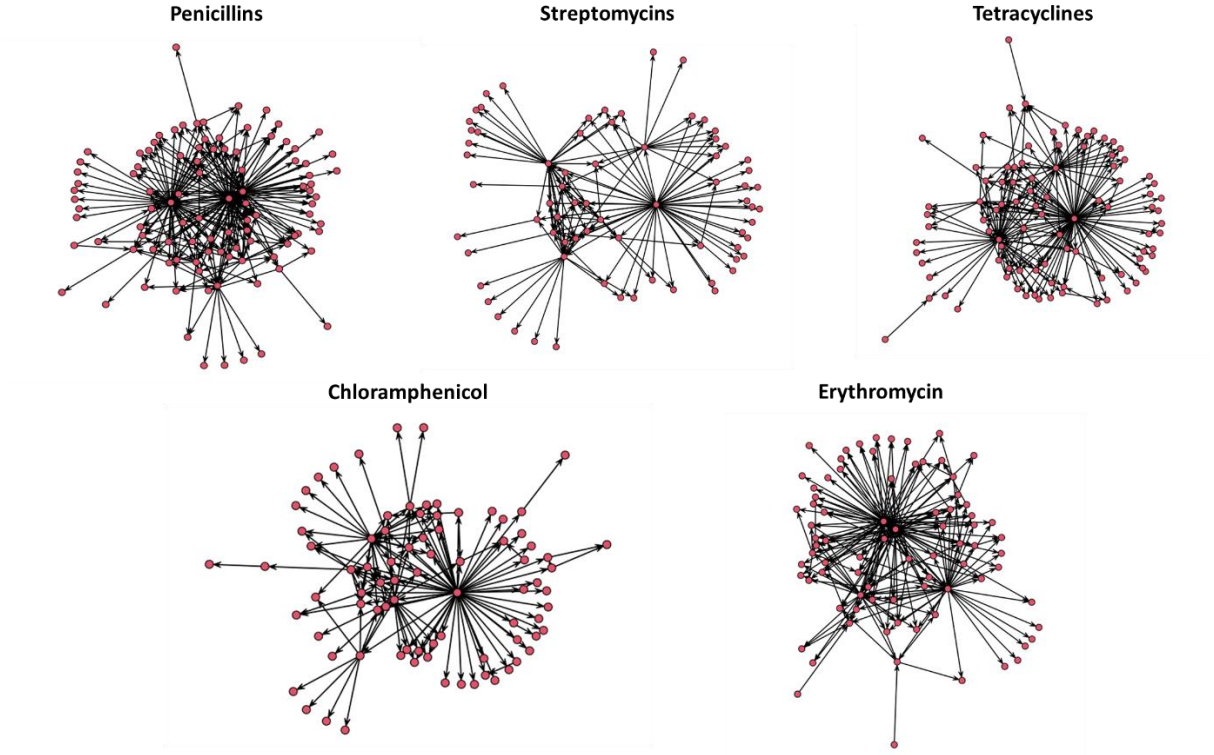
3.2 Characteristics of Global Trade Networks

A qualitative analysis of the existence of trade relationships provides information on the structure of the trade networks. Figure 3 provides a structural representation of the networks of the five product groups of antibiotics in the observation year 2021. The dots symbolize trading countries, the directed arrows the existence of bilateral export flows. Despite numerous peculiarities, some commonalities can be diagnosed. For all product groups, several export hubs can be identified in the global network, around which numerous importing countries are grouped that mostly do not act as exporters themselves. The export hubs are also linked directly and indirectly (via intermediaries) with one another. One cannot therefore speak of fragmented trading silos, but rather of a globally integrated network of local export centres. This is particularly true for penicillin, whose trade is characterized by many

connected hubs and complex bridges of intermediaries. In the case of streptomycin and chloramphenicol, the structures are less complex in comparison, with a smaller number of hubs which are less closely linked to one another.

An examination of the geographic patterns provides more details about the character of the networks. Figures A1-A5 in the appendix depict the networks as trade flows on the world map. The thickness of the arrows symbolizes the share of the trade flow in the global trade value of the respective product. This shows that in 2021, the People's Republic of China was clearly the most important export hub globally for all product groups considered. Most pronounced is the dominance in the case of Chloramphenicol, where China as a source accounted for more than 90 % of all reported imports at the global level. Differences can be seen above all in the geographical concentration of Chinese imports. While in the case of penicillin and erythromycin, Chinese exports are very diversely distributed globally, the other groups show a clear focus on exports to the EU in terms of product value. In the case of penicillin and erythromycins, the close trade relations with India, which itself acts as an export hub with relations to numerous countries and almost all regions of the world, can also be identified as a special feature. This illustrates the relevance of an investigation into possible network risks for these product groups.

Figure 3: Trade networks of antibiotic classes in 2021 – structural representation



Source: own illustration.

A comparison with the geographical pattern from 2001 provides indications of significant structural changes in the global antibiotics trade within the last two decades. In particular, the loss of importance of the EU as an exporter is striking for all product groups considered. This is especially true for penicillin, where the EU-USA route was by far the most important trade relationship globally in 2001. However, for the other products as well, the EU has lost some of its centrality in the global network, both quantitatively (importance of exports in terms of value) and qualitatively (number of import partners, geographical spread). Moreover, for penicillin and tetracyclines, the import side shows a significant

decline in the importance of the USA. This is an indication of geographical shifts in the downstream segment (production of finished medicines).

Finally, changes in the trade structure can also be documented analytically, based on indicators for the global description of networks. Table 3 shows a selection of common indicators for the observation periods. A similar pattern emerges across products. For four of the five product groups, transitivity as a measure of the level of clustering in the network has decreased significantly over the 20-year comparison (exception: streptomycin). The density of local trade clusters has thus declined in these groups relative to the density of the global trade network. In line with this observation, modularity as a measure of the strength of the segmentation of the global network into local sub-networks has also shrunk significantly for penicillin and chloramphenicol. The degree of cross-cluster trade integration has thus increased, at least for these groups. At the same time, however, the density of the global network has decreased for all groups. Overall, trade relations have thus become somewhat more linear and less complex.

Table 3: Indicators of global network properties

Name	**Transitivity**	**Network density**	**Largest eigenvalue**	**Modularity**	**Avg. degree centrality**
Measure	Relative intensity of trade among network neighbours	Relationship of the number of linkages to the size of the network	Largest (real) eigenvalue of the adjacency-matrix of the network	Relationship of community-internal to community-external linkages	Average of country-specific degree centralities
Interpretation	Clustering tendency of networks	Complexity of network relations	Inverse measure of the shock resilience of networks (see Wang et al.)	Strength of segmentation of the global network into local networks	General degree of diversification of trading partners
2021					
Penicilins	0.104	0.026	3.365	0.040	5.172
Streptomycines	0.134	0.027	1.325	0.205	3.786
Tetracyclines	0.093	0.024	2.636	0.078	4.429
Chloramphenicol	0.100	0.022	0.000	0.040	3.613
Erythromycin	0.131	0.035	3.183	0.040	5.633
2001					
Penicilins	0.155	0.034	4.943	0.181	3.628
Streptomycines	0.123	0.028	1.893	0.102	1.676
Tetracyclines	0.132	0.030	3.341	0.075	2.670
Chloramphenicol	0.124	0.026	2.066	0.187	2.176
Erythromycin	0.189	0.037	4.226	0.042	2.686

Source: own calculations.

Finally, according to Wang et al. (2003)[76], statements about the network's resilience to the transmission of local shocks can be derived from the web of direct trade relationships. The relevant indicator is the largest real eigenvalue of the network's adjacency matrix. A high value represents high vulnerability, in the sense of faster transmission of shocks throughout the network. Accordingly, vulnerability has decreased for all product groups over the 20-year comparison. This can be understood as a consequence of the lower network density. However, this result says nothing about the local vulnerabilities of individual countries. These also depend crucially on the weighting of the edges (importance of

[76] Wang, Y.; Chakrabarti; D., Wang, C.; Faloutsos, C. (2003), Epidemic spreading in real networks: An eigenvalue viewpoint. In 22nd International Symposium on Reliable Distributed Systems, 2003. Proceedings. (pp. 25-34). IEEE.

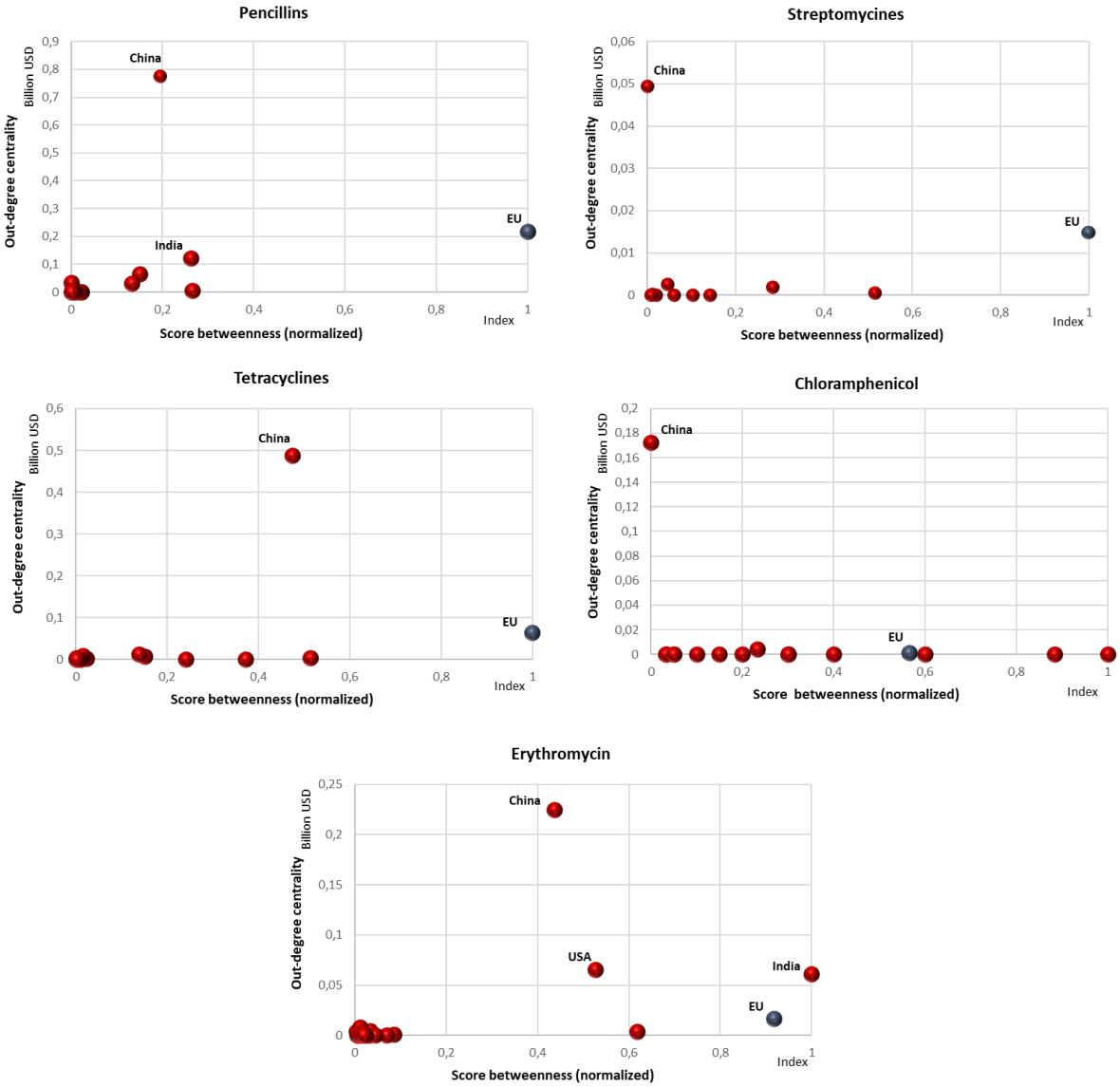
imports from individual countries) and country-specific risks/shock probabilities. To fathom these forthe EU requires a closer analysis of its role in the current networks.

3.3 The EU Position in Trade Networks

A look at node-specific network indicators reveals the EU27's significant position in international trade in all five classes of antibiotics. This is reflected in the large number of direct trading partners. For penicillin, streptomycin, tetracyclines and chloramphenicol, the EU had the second-most trading partners after China, and for erythromycin the third-most (behind China and India). Thus, the role of the EU27 in the network also significantly exceeds that of the USA, Japan, and other advanced economies in each case. This indicates a particular sensitivity of EU27 demand to disruptions in the trade network, as it could thus potentially be affected by a variety of local trade shocks.

The role of the EU27 becomes even clearer when the direction and volume of trade flows are included in the analysis. Figure 4 shows the calculated values of individual nodes for two key indicators: *weighted out-degree centrality* and *betweenness*. Out-degree centrality measures the importance of nodes in the network based on the edges emanating from the nodes, i.e. the extent of individual export relationships. Here, the trade value is used for weighting, i.e. we de facto measure the total values of exports of the respective nodes. The betweenness measures the number of instances where the shortest link between a pair of nodes in the network passes through the node under consideration. It is thus a measure of the global importance of the node as an intermediary, i.e. it reflects the combined influence as an importer and exporter. In the year 2021, the EU was not nearly as important as China in terms of out-degree centrality, but it was still a very important global intermediary, unlike China, which was one-sidedly export-focused. In the case of penicillin, streptomycin and tetracyclines, the EU was even by far the most important global interface. An analysis of the sourcing risks for the EU27 is therefore also of indirect relevance for other import regions.

Figure 4: Distribution of out-degree centrality and betweenness scores in 2021



Source: own calculations.

3.4 Exposure to Network Risks: First Estimates

A global view of trade networks is insufficient to assess country- or region-specific risks. Indicators are needed which identify existing supplier-specific risks and weight them according to the mix of trading partners in the respective importing country. In addition to direct risks, indirect risks should also be mapped, as they arise from the activities of intermediaries in the trade network. The literature on network analysis has developed several approaches in recent years to analyse the transmission of contagious shocks in complex networks.

In relation to trade networks, Klimek et al. (2015) developed an indicator for systemic trade risks and tested it using the example of international trade in rare earth metals.[77] It is based on the Page Rank

[77] Klimek, P.; Obersteiner, M.; Thurner, S. (2015), Systemic trade risk of critical resources. Science advances, 1(10), e1500522.

Algorithm originally developed by Google for evaluating the influence of web pages.[78] Its basic principle is to measure the influence of a node by the influence of its neighbours. Influence is thus seen here as a form of mutual dependence. The importance of individual neighbouring nodes in the calculation can be influenced by the choice of an exogenous weighting factor. Intuitively, the page rank measures the probability of reaching the node in question after a certain (large) number of steps, starting from a random node and traversing the network. To avoid problems in connection with dead ends or loops, the algorithm contains a stochastic component, the damping factor. It expresses the probability of a step jumping to a random point in the network. It is therefore a measure of the unpredictability of the network relationships.

Klimek et al. (2015) reinterpret the page rank indicator by not simply using the bilateral trade value as a weighting factor for individual edges, but instead the product of import share and supply risk. As an expression for supply risk, they propose a measure of the political instability of the supplier country, derived from the corresponding WGI indicator of the World Bank (see Section 2.4). In this way, the Page Rank indicator becomes a measure of systemic (i.e. network-related) trade risk caused by political instability. The systemic trade risk is estimated to be high for those countries that have close trade ties with countries sourcing their imports from suppliers with low political stability. In this way, it considers that a country can be affected by supply disruptions in unstable countries even without a direct trade connection, due to the disruptions spreading across the trade network.

In the following, we are interested in the network contagion of regulatory risk, i.e. unforeseen changes in trade, health or industrial policies in supplier countries. Ideally, regulatory risk would be measured in a product-specific and multidimensional form, based on expert assessments and policy experiences. Such specific indicators are currently not available. For our example analysis, we resort to a macro indicator. We follow the approach of Klimek et al. (2015), with the exception that we use the WGI indicator "Regulatory Quality" ($RegQual$) instead of political stability. Specifically, we use the following weighting factor for each trade connection in the page ranking algorithm, where exporter i is exporting products of value $Trade_{ij}$ to importer j:

$$Weight_{i,j} = (1 - RegQual_i \,/\, 100) \times \left(Trade_{ij}/Total\ imports_j\right)$$

The resulting page rank estimates can be interpreted as a measure of network-related trade risks. Specifically, they measure a node's average supply loss (in relative terms) caused by an export stop by a random node in the network. In this context, the damping factor can be understood as a measure of supply risks from exogenous influences unrelated to the network structure.[79]

Table 4 presents the countries with the highest estimated network-related trade risks for the product groups considered, compared with global averages and values obtained for the EU27-node. It reveals a highly product-specific pattern, but with some countries, such as Oman, exhibiting consistently scores way above the global average. The overall frequency distributions of scores are in each case clearly right skewed, i.e. low values cluster in a small range near the mean, while high values are distributed along a larger range. **For the EU27, way above average network risks were measured for all antibiotics except Chloramphenicol**. Concerning Erythromycin, the EU27 belonged in 2021 to the

[78] Page, L.; Brin, S.; Motwani, R.; Winograd, T. (1998), The pagerank citation ranking: Bring order to the web. Technical report, Stanford University.

[79] Klimek et al. (2015). Consistent with a common convention, we set the damping factor equal to 0.85.

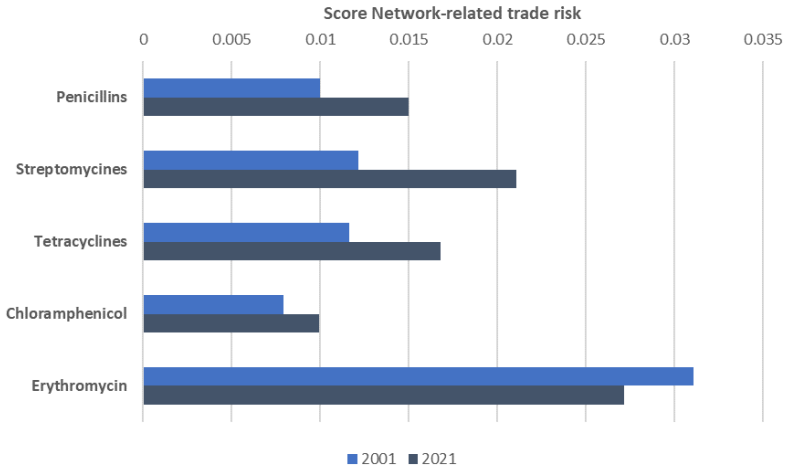
riskiest trade nodes worldwide. Figure 5 shows the comparison to values obtained based on trade data from the year 2001. **Accordingly, the relative risk position of the EU27 in the global trade network has clearly worsened for four of the five classes of antibiotics investigated.**[80]

Table 4: Results for the indicator of network-related trade risk in global comparison

Rank	**Penicilins** Country/Region	Value	**Streptomycines** Country/Region	Value	**Tetracyclines** Country/Region	Value	**Chloramphenicol** Country/Region	Value	**Erythromycin** Country/Region	Value
					2021					
1	Kirgistan	0.0284	Honduras	0.0338	Oman	0.0482	India	0.0428	Oman	0.0440
2	Oman	0.0278	Armenia	0.0311	Ethiopia	0.0228	Nigeria	0.0396	**EU27**	**0.0271**
3	Kazakhstan	0.0247	Canada	0.0236	Mongolia	0.0213	Uruguay	0.0302	New Zealand	0.0237
4	Ecuador	0.0239	Egypt	0.0230	Singapore	0.0187	Norway	0.0263	India	0.0233
5	Bolivia	0.0237	New Zealand	0.0221	Armenia	0.0182	Ecuador	0.0247	Guatemala	0.0223
	Global average	*0.0099*	*Global average*	*0.0136*	*Global average*	*0.0106*	*Global average*	*0.0122*	*Global average*	*0.0124*
	EU27	**0.0150**	**EU27**	**0.0211**	**EU27**	**0.0168**	**EU27**	**0.0099**	**EU27**	**0.0271**

Source: own calculations.

Figure 5: Time comparison of the network-related trade risk indicator for the EU27



Source: own calculations.

When interpreting these results, it is important not to confuse them with the direct trade risks analysed in Section 2.4. The direct trade risks measure the risks emanating from the importing entity's immediate trade partners. Instead, the page rank indicator measures the average risks emanating from all nodes in the trading network, with the risk of a shock spreading through a trade connection determined by the regulatory quality measure and the trade value. For instance, the particularly high network-related risk estimated for Oman's access to Erythromycin can be explained as follows: it exhibited strong net import connections with China and Egypt, which, in turn, were part of a central bi-directional sub-network of trade among nodes with mostly low regulatory quality. In the same vein, the

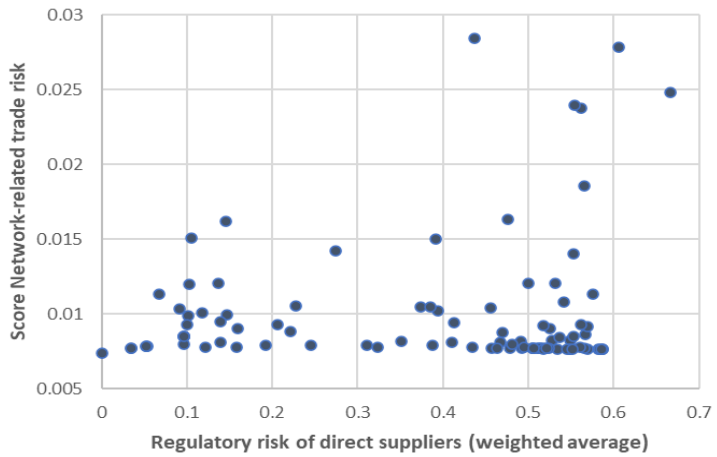
[80] Note that, since Page Rank scores of different nodes in each year add up to one, this only measures the relative risk exposure compared to other nodes and does not account for any potential change in the "global riskiness" of the trade network as a whole.

relatively high risk measured for the EU27 for the same product is attributable to its strong attachment to parts (China and India) of the same sub-network.

Moreover, the results do not involve any information on the degree of import dependence. Only bilateral trade flows, no (so far at the global scale non-existing) data on country-specific production or consumption has entered the analysis. Network-related trade risks thus need to be carefully distinguished from the exposure to supply risk caused by insufficient domestic production capacities.

Hence, a useful role for such a network-based risk indicator does not lie in replacing or adjusting established simpler measures but complementing them to produce a fuller picture. This is further supported by a look at the common distributions of the network-related risk measure and the average weighting factors (see above) applied only to direct suppliers. In every antibiotic class, the correlation between the two measures is positive, but only weakly. Figure 6 illustrates this fact for the example case of penicillin.

Figure 6: Comparison of network-related and direct trade risks



Source: own calculation.

4 Instruments for Risk Management

4.1 Instruments under Discussion

The preceding analysis has shed light on the existence of several dimensions of supply risk. It has further documented signs of a risk increase in the considered dimensions. This fact alone, however, does not justify any regulatory intervention, as risks are spread through market repercussions, not in the form of external effects. Social costs do however arise due to the lack of insurability. Many critical medicines have no possibility of technical substitution in the short term. And market-based insurance by way of hedging instruments cannot account for the societal impact of supply failures. This impact is potentially of a far-reaching and non-economic nature, as it threatens the well-being or even the lives of the vulnerable part of the population. Therefore, it is a public responsibility to engage in risk prevention and management.

Ideas for concrete measures to combat the emergence or consequences of medicine shortages have already been voiced by various institutions. For example, the study “Future-Proofing pharmaceutical legislation” on behalf of the Commission in 2021 contains a number of corresponding proposals to

stakeholders at various levels.[81] The Structured Dialogue on Medicines Security has also provided starting points for future action.[82] Moreover the Member States behind the Non-paper bring measures of the Critical Raw Materials Act and the Chips Act into play as potential role models.[83] Finally, the Commission's proposal for a reform of pharmaceutical legislation has also included a range of instruments specifically designed to strengthen supply security.[84]

The range of conceivable measures is broad and differs above all in terms of the strength of the intervention and the addressed stakeholder level. However, what they have in common is that their implementation requires close cooperation between the stakeholders involved, both at the level of the legislative bodies (EU and Member States) and between the actors in the supply chains (producers, wholesale and retail traders, actors in the health system). Table A1 in the Appendix represents an attempt to summarize a selection of relevant instruments. The instruments are compared regarding their level of application, and possible (design-dependent) potentials and dangers are identified. We distinguish between a static perspective, which evaluates the instruments based on the current supply mix, and a dynamic perspective, which considers their potential impact on the future development of the supply mix.

While all instruments have their specific merits, many of them are likely to cause significant trade-offs with goals like cost efficiency and long-term capacities to innovate. It is therefore crucial to establish an instrument mix that is internally consistent and does not conflict with other strategic goals of the EU, especially in the fields of innovation, competitiveness, and green transformation. In the following, we present our own recommendations designed to support the establishment of an effective and sustainable framework for critical medicines.

4.2 Recommendations

Experiences with the COVID-19 pandemic have shown: a lack of coordinated action during a health crisis entails high costs. This also applies to access to medicines. But even beyond temporary crisis situations, there is a threat of future shortages in access to essential APIs, primarily resulting from increasingly complex supply chains. For the EU, the risks of such shortages threaten to intensify if it continues to lose ground as a location for innovation and production of pharmaceuticals in competition with the USA and Asia.

The calls by the concerned EU Member States, for a Critical Medicines Act which focusses on shortage risk monitoring and response, are therefore justified**. It is incomprehensible why the EU is discussing a Critical Raw Materials Act with profound risk management measures, while shortage risks in the medical sector, which is clearly more essential for social welfare, are not addressed by a specific piece of legislation.**

At the same time, however, any legislative plan must consider the significantly higher degree of complexity compared with mineral raw materials, starting with the multi-layered and (globally and within the EU) heterogeneous regulatory framework, through to the high degree of differentiation in the

81 European Commission (2021), Future-proofing pharmaceutical legislation —study on medicine shortages. Final Report. Study by Technopolis Group, Ecorys BV, Milieu Law & Policy Consulting for the European Commission. December 2021.

82 European Commission (2022), Vulnerabilities of the global supply chains of medicines - Structured Dialogue on the security of medicines supply. Commission Staff Working Document.

83 Non-paper on security of medicines supply, p. 3.

84 COM(2023) 193 and COM(2023) 192; see upcoming cepPolicyBrief.

supply chains. Against this background, shortage risks are highly product-specific, multi-layered and, in view of complex interactions, not easy to identify.

It is therefore crucial that the EU does not take the second step before the first in developing risk management tools. An expanded risk monitoring framework must first be created as a foundation before instruments of market intervention are conceptualized. Given the high information costs implied by diversity of medicinal products, this requires strict prioritization. In view of the fundamental consequences that a categorization of products as "critical medicine" can have for the well-being of citizens, such prioritization must in any case be based on objective, scientifically well-founded criteria. In a subsequent step, a risk management framework should be established for products classified as critical. This must be kept as lean as possible, the intensity of its market interventions must be proportionate to the development of the shortage risk, and it must not overburden the stakeholders in the healthcare system with additional bureaucracy.

Against this background, we make the following concrete recommendations, structured into short-term and long-term measures.

1. Short-term: Develop a common framework for measuring trade-related risks

The fact that therapeutic benefit is prioritised as a criterion in the EU Draft Methodology for the selection of critical medicines is undoubtedly correct. However, the development of a coherent framework for the measurement of shortage risks, especially supply-chain related risks, should be pursued in parallel. As medical significance is also subject to technological dynamics, such a framework should be applied to the entire spectrum of medicines (not only potentially lifesaving medicines). This requires a suitable categorization to reduce complexity and monitoring costs. Attempts to measure supply-chain-related risks purely ex post on the basis of past shortage situations are insufficient in view of the strong market dynamics. A sound methodological framework requires the use of indicators for the ex ante measurement of risks, including established advanced statistical techniques like network analysis (see our example analysis).

2. Short-term: Extend the toolbox and data availability for targeted risk diagnosis

The measurement of risks from global supply chains and trade networks requires a highly product-specific database. In the absence of global comparative data on production capacities and consumption, foreign trade data still provides the best data basis for this purpose. However, they are also limited in their product-specific resolution. The EU, in cooperation with the relevant statistical offices, should establish channels for the regular supply of foreign trade data beyond the resolution provided in publicly available figures. To account for the geopolitical level of supply-chain-related risks, indicators for measuring country risks for supply from third countries should also be included in the risk monitoring methodology - along the lines of the existing EU methodology for critical raw materials. These should, as far as possible, illuminate both the general policy level and the specific regulatory level (risk of supply-disrupting policies). For the latter, ideally a set of indicators structured according to policy areas (e.g., trade policies, approval practices, R&D policies) should be developed. Indicators to measure the sustainability of current supply routes would also be a useful extension of the information base against the background of the EU's Green Agenda.

3. Short-term: Evaluate the needs for stockpiling on a product-specific cost-benefit basis

In its feasibility study on the stockpiling of antibiotics, HERA identified this instrument as a promising way to mitigate shortage risks due to supply chain disruptions. HERA recommends the buildup of a 4-8 weeks physical stockpile through the RescEU system, as well as improved coordination of existing stockpiling obligations at the level of Member States.[85] In principle, stockpiling can support an effective short-term response to crisis situations also for other categories of risk-prone medicine. However, as also pointed out by HERA, this must be weighed against the costs of maintaining inventories. If stockpiling is implemented as a producer obligation, this could, considering existing price pressure, further worsen the margin situation for the European Pharma sector and thus run contrary to the goal of securing a stable domestic supply base. If it is implemented as a stock held and managed by public entities, incentive issues may arise: the lack of personal economic incentives of decision-makers will threaten the alignment of stockpile management with market needs. Moreover, in the event of a crisis, a central EU stockpile will unavoidably provoke distribution issues, including potentially fierce political debate between and within Member States. Therefore, decisions on the necessity and appropriate level of stockpiling medicines need to be based on a fully fledged cost-benefit analysis (including an investigation into market repercussions) for specific product categories. The existing HERA report on the case of antibiotics represents an appropriate role model for this.

4. Short-term: Review and extend existing support channels for R&D-spending

Europe's loss of market share in medicinal R&D is an ominous warning signal. In addition to long-term improvements in domestic production conditions, the EU should already now examine the scope and focus of its arsenal of public R&D funding in the medicinal sector, especially in areas of APIs, where the EU has lost ground compared to global competitors. The extension of the EU budget framework, the expansion of public-private co-spending under the umbrella of the research program Horizon Europe and the Innovative Health Initiative are first steps in this direction. However, to avoid a crowding out of private sources of capital and to increase the targeting, the EU and the Member States should take complementary measures to strengthen purely private funding channels. In particular, access to private venture capital, which plays an increasingly important role in global R&D spending in the field of medicine, should be improved. Here, it is primarily the Member States that are called upon to set appropriate incentives through tax policy.

5. Long-term: Create the fundaments for domestic cost competitiveness

Supply security for critical medicines requires a solid fundament of domestic production capacities, especially in the field of hard-to-replace APIs. To guarantee this for the future, EU and Member States should jointly work upon ways to improve the competition conditions for the domestic chemical and pharmaceutical sector, without causing additional market distortions. The appropriate lever is the cost side. On the one hand, this concerns the costs resulting from regulatory complexity. Efforts to streamline existing regulation must be intensified, in order to reduce the EU-internal costs of regulatory compliance for pharma producers. It also concerns energy costs, especially in recent times. The EU is called upon to press ahead quickly with its current reform projects to expand and integrate renewable energies, as a prerequisite for curbing electricity prices in the long term. Where alternative technologies

[85] European Commission (2022). HERA AMR feasibility study on stockpiling – D6/D7 Final report. Written by McKinsey Solutions, September 2022.

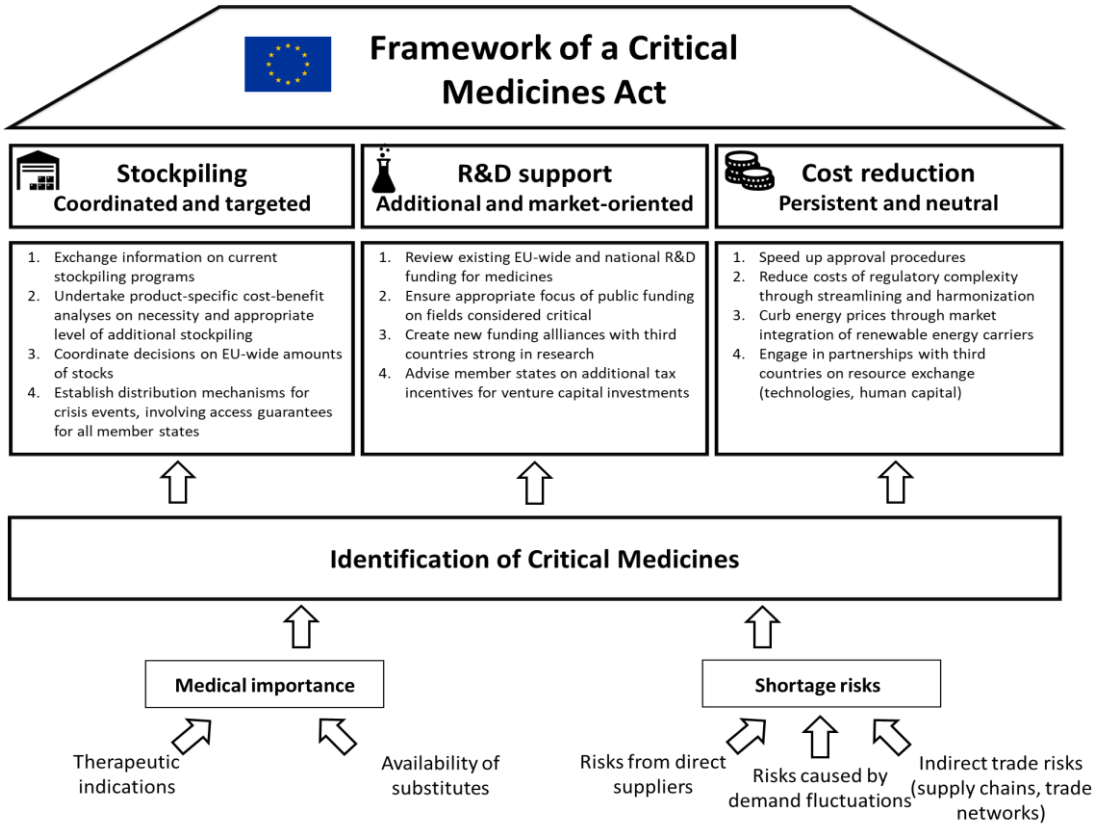
are available, firms should also be supported in reducing their dependence on natural gas and other fossils.

6. Long-term: Extend cooperation with reliable third countries

Improving supply security is a costly endeavour. To limit wasting its own resources, the EU must continue to rely on the potential of an international division of labour. One approach already discussed in the context of critical mineral raw materials is the development of deeper partnerships with like-minded third countries. One example in the health sector is the EU-LAC partnership on health, which was signed in June 2022. This agreement between the EU and numerous Latin American and Caribbean countries aims to improve production capacities and access to medicine in partner countries by strengthening technology transfer and regulatory cooperation.[86] This agreement, which itself focuses more on development policy, could serve as a blueprint for more symmetrically designed agreements that also support production and supply in the EU. Such partnerships could include forms of long-term cooperation through knowledge sharing, joint research, infrastructure development and regulatory harmonization. All these measures are aimed at creating new stable supply chains. One particularly relevant area of regulatory cooperation could be the harmonization or mutual recognition of approval procedures for new medicines.

Figure 7 summarizes our central policy recommendations in the form of a three-pillar-strategy.

Figure 7: Proposed framework of a future EU Critical Medicines Act



Source: own illustration.

[86] European Commission (2022). EU-Latin America and Caribbean Partnership: manufacturing vaccines, medicines and health technologies and strengthening health systems. Press release, 22 June 2022.

5 Conclusion

Medicine shortages represent a growing threat to public health. The root causes are multifactorial, including but not limited to supply chain disruptions and vulnerabilities affecting the supply of key ingredients. The COVID-19 pandemic has exacerbated the situation. This is why many countries are now pursuing policies aimed at improving the monitoring, mitigation, and prevention of future shortages. Yet, overall, the complexity of medicine shortages renders simple explanations insufficient and single policy measures inadequate.

Against this background, 19 Member States recently agreed to a "Non-paper" in which they emphasise that the EU is becoming increasingly dependent on imports from a few manufacturers and a few regions. These Member States are calling for different points of action, among them, a new legal framework to reduce dependencies for critical medicines and ingredients, particularly for products were there are only a few supplying manufacturers or countries. Specifically, they want to follow the example of the Critical Raw Materials Act and ask the Commission to present a proposal for a Critical Medicines Act.

This article takes this demand as a starting point to analyse current risks in the access to different groups of medicinal products and to provide recommendations for risk classification and policy instruments. In doing so, we take a trade-oriented view and focus on risks related to the EU's current trading partners and its positioning in the global trade network of medicinal products. First, we argue that the complexity of interactions in medicine supply requires a clear theoretical division of risk factors into root causes, crisis triggers and amplifiers. Second, we argue that an operationalization of shortage risks into measurable, updatable indicators has to become an integral part of future EU-wide risk management. In this regard, the reporting on critical raw materials can serve as a role model, which however requires serious modification to account for the peculiarities of the markets for pharmaceuticals in the EU. Third, given the complexity of supply chains and trade networks, with their hidden dependencies and contagion risks, we argue that a serious risk analysis should not be limited to the EU's immediate trading partners.

Empirically, our results first highlight the existence of EU import dependence and policy-related supply risks, mainly for the product stage of APIs. Especially for antibiotics, hormones, and glycosides, we identify an upward trend in supply risks related to both the political stability and regulatory quality of the EU's trading partners. Such shortage risks threaten to intensify if Europe continues to lose ground as a location for innovation and production of medicines in competition with the USA and Asia. Second, by performing a comprehensive and detailed network analysis for international trade in five antibiotics classes, we demonstrate the need for a product-specific view of medicine trade and the important role of network dependencies. Based on a novel indicator for systemic trade risk, we show that between the years 2001 and 2021 the EU's exposure to regulatory risks has clearly worsened compared to other regions for four of the five classes of antibiotics investigated.

The call of the concerned Member States to learn from the experiences with the Critical Raw Materials Act and to enact a Critical Medicines Act are therefore justified. However, any such legislation must consider the significantly higher degree of complexity compared with the situation of raw materials. To account for this complexity, we propose a series of six steps that pave the way towards a future Critical Medicines Act. A more detailed risk measurement and the development of an adequate and robust methodology for defining critical medicines need to be at the forefront of all efforts by the EU.

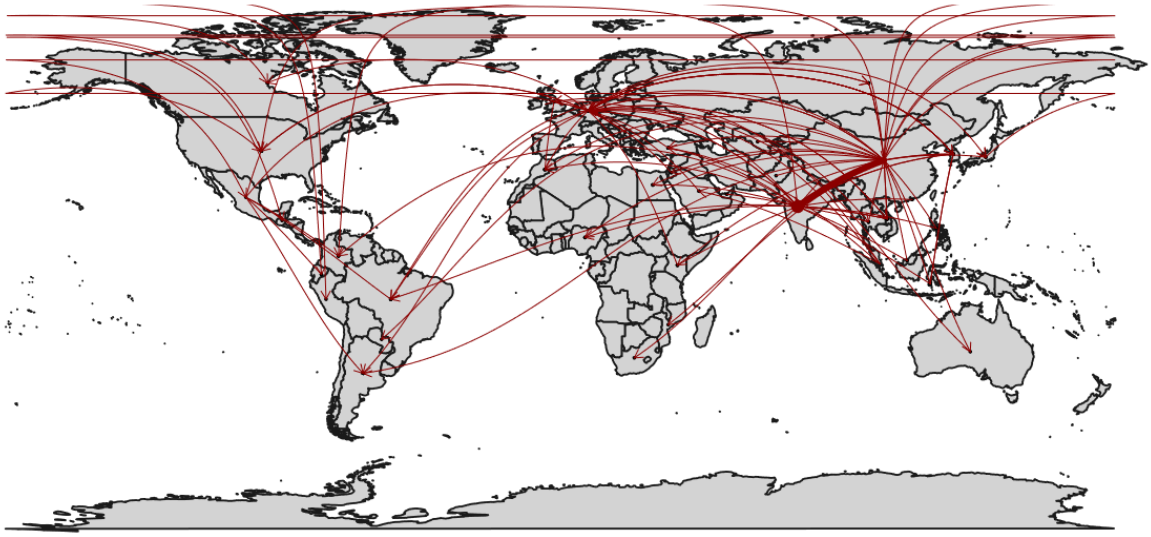
On this basis, we propose several complementary short- to long-term measures to increase supply security for critical medicines, which can be grouped into a three-pillar strategy. The first pillar consists of the development of an EU-wide stockpiling strategy. Since stockpiling involves costs, this requires a careful investigation of the appropriate level of implementation, and the execution of product-specific cost-benefit analyses. The second pillar consists of measures to enhance the effectiveness of public R&D support. Current support channels should be reviewed and streamlined, and access to private venture capital improved. The third pillar comprises measures to improve the cost-related competitiveness of the EU as a production location for medicinal products. This starts with a reduction of costs resulting from regulatory complexity and ends with a determined expansion of renewable energies to cut energy prices.

Altogether, when establishing a framework for critical medicines, one must bear in mind that the diversity of medicines gives rise to high information costs. This in turn requires a strict prioritisation based on objective, scientifically well-founded criteria. The framework of identified “critical“ medicines must be kept as lean as possible, in order to maintain proportionality in the intensity of market interventions and to ensure that stakeholders in the healthcare system are not overburdened.

6 Appendix

Figure A 1: Global network of trade in Penicilins (HS Code: 294110)

Year 2021:

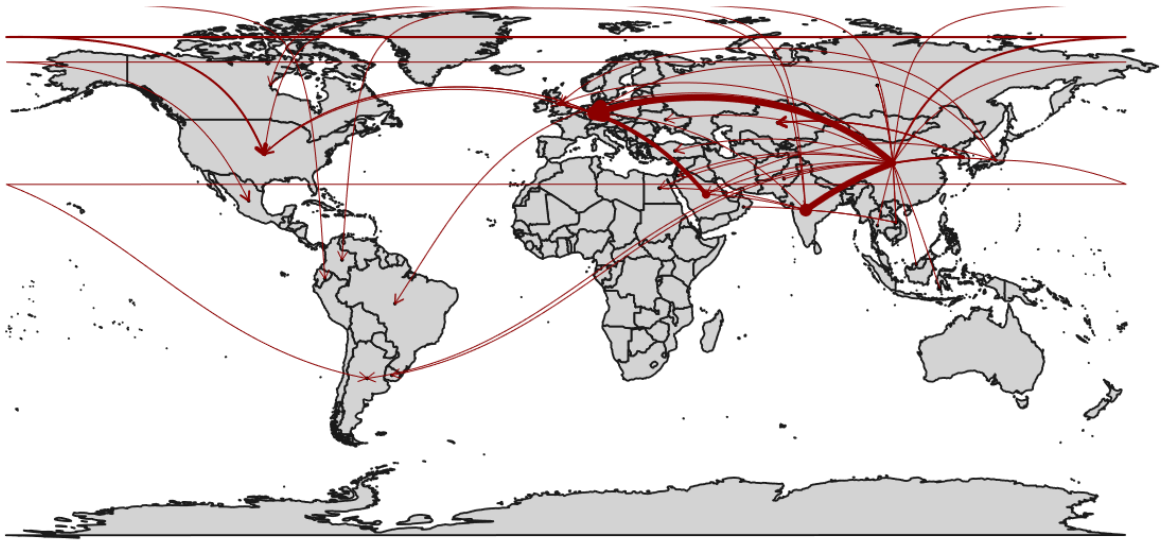


Year 2001:

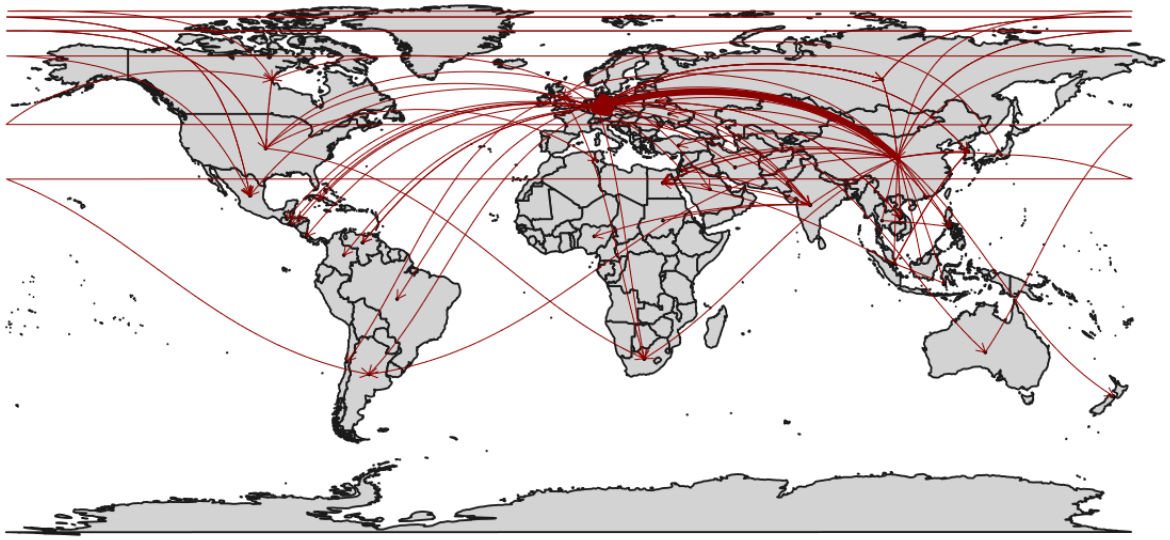
Source: Own illustration; only connections visualized > 0.1 % of global trade volume; EU27 treated as one node. Thickness of lines: Share in global trade value of the respective year.

Figure A 2: Global network of trade in Streptomycins (HS Code: 294120)

Year 2021:



Year 2001:

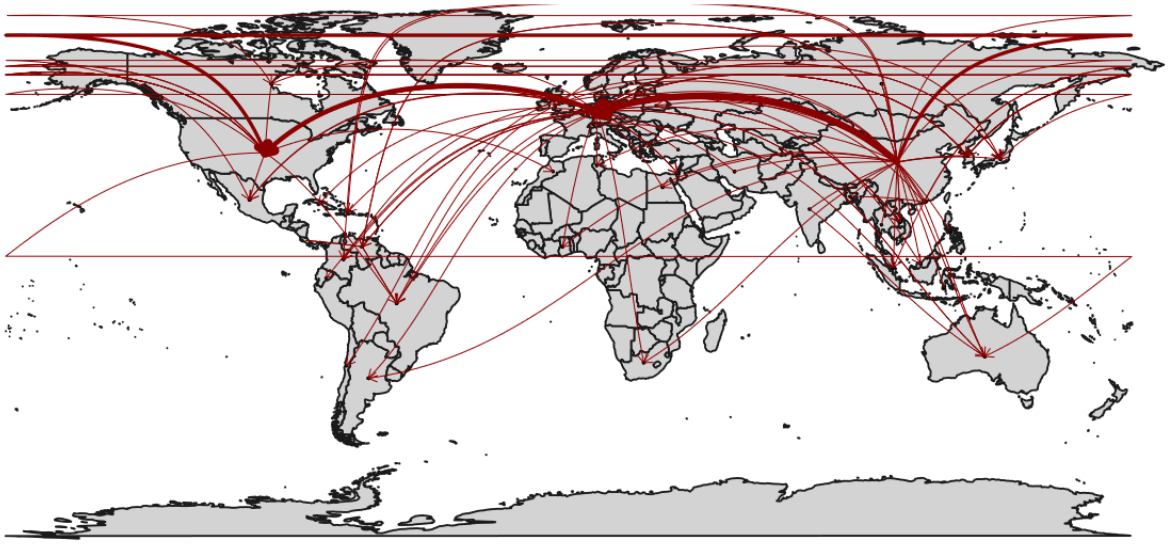


Source: Own illustration; only connections visualized > 0.1 % of global trade volume; EU27 treated as one node. Thickness of lines: Share in global trade value of the respective year.

Figure A 3: Global network of trade in Tetracyclines (HS Code: 294130)

Year 2021:

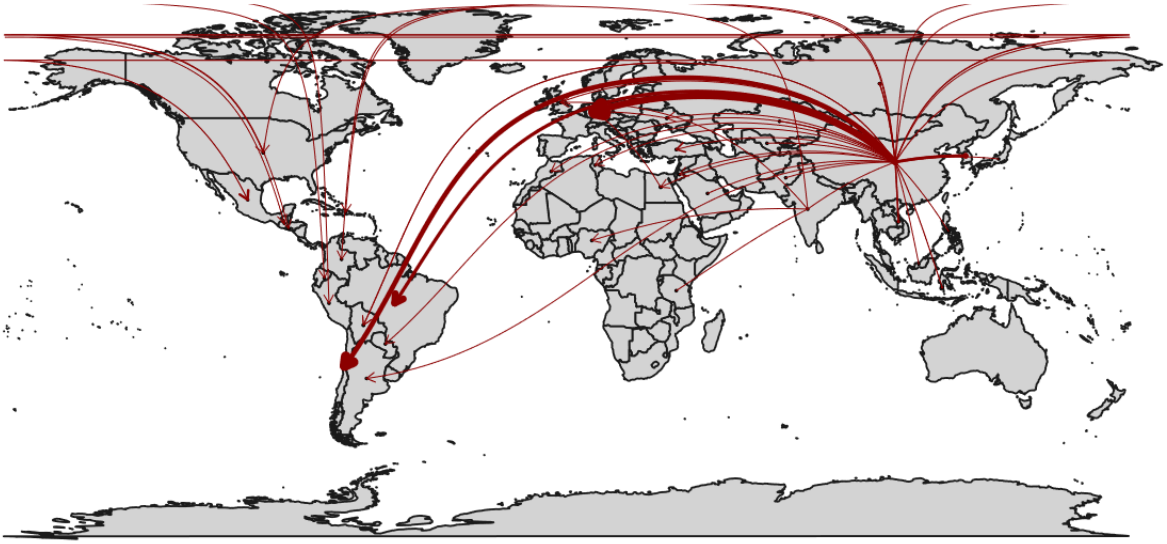
Year 2001:



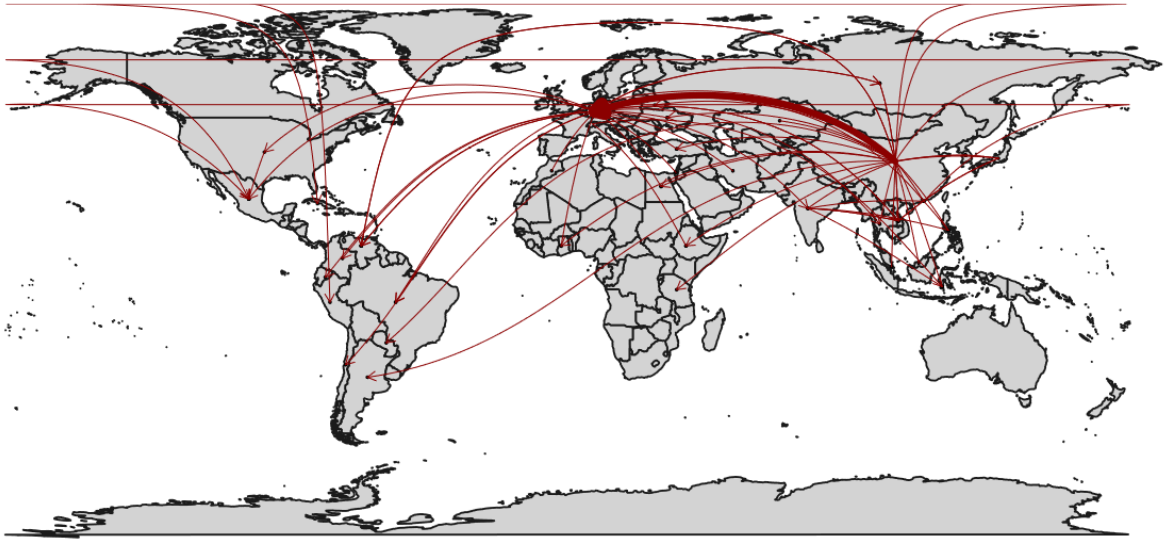
Source: Own illustration; only connections visualized > 0.1 % of global trade volume; EU27 treated as one node. Thickness of lines: Share in global trade value of the respective year.

Figure A 4: Global network of trade in Chloramphenicol (HS Code: 294140)

Year 2021:



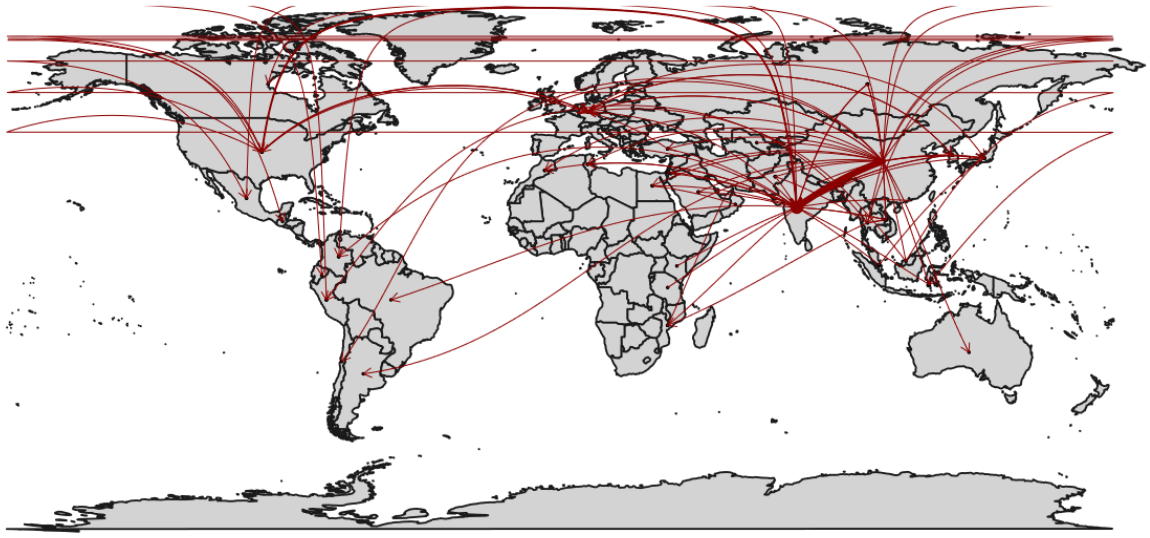
Year 2001:



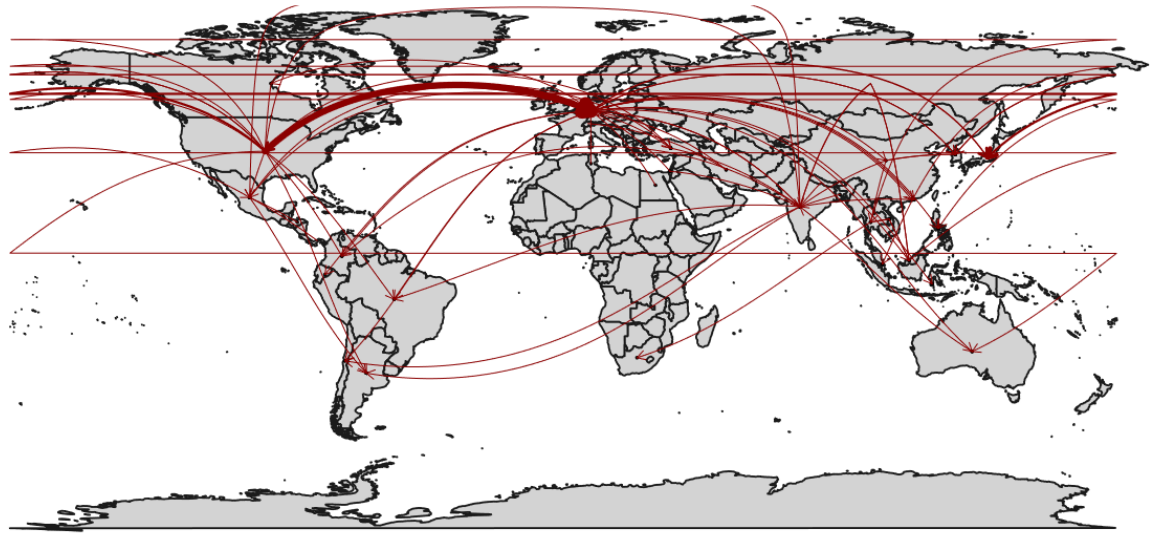
Source: Own illustration; only connections visualized > 0.1 % of global trade volume; EU27 treated as one node. Thickness of lines: Share in global trade value of the respective year.

Figure A 5: Global network of trade in Erythromycin (HS Code: 294150)

Year 2021:



Year 2001:



Source: Own illustration; only connections visualized > 0.1 % of global trade volume; EU27 treated as one node. Thickness of lines: Share in global trade value of the respective year.

Table A 1: Overview of potential instruments to tackle shortage risks in medicinal products

Instruments	Risk categories addressed (see Figure 2)	Implementation			Repercussions on health system efficiency			
					Static perspective		*Dynamic perspective*	
		Legislative change required (yes/no)	Actors responsible for implementation	Difficulty to implement	Potentials	Dangers	Potentials	Dangers
Overarching								
Stakeholder coordination*	Triggers	No	Stakeholders supply chain	Low	Improved information exchange on bottlenecks		Joint development of new stable supply channels	
Stronger EU-wide alignment of packaging regulations*	Amplifiers	Yes	EU; Member States	Low	Facilitating exchange of medicines in crisis situations		Lowers costs of cross-national market entry	
Accelerated authorisation procedures*	Roots, Triggers	Yes	EU; Member States	Medium	Saves costs for developers		Boosts EU innovation activity	
Public stockpiling of critical medicines	Triggers, Amplifiers	Yes	EU; Member States	Medium	Faster internal compensation of supply disruptions			Distribution issues; Lack of efficiency due to missing incentives
Field 1: Measures targeting suppliers in general								
Stronger sanctions enforcement against unreliable suppliers	Triggers	Yes	Member States	Medium	Stronger incentives to fulfill supply obligations	In absence of harmonization: internal market distortion		Lowers attractiveness of EU markets
Transparency requirements on quotas for supply to wholesalers	Triggers	Yes	EU; Member States	Medium	extended information base for shortage predictions			Lowers attractiveness of EU markets
Obligation to prepare risk monitoring and mitigation plans*	Triggers, Amplifiers	Yes	EU; Member States	Low	Improved risk awareness and preparedness	Additional bureaucractic burden		
Obligations for producers or wholesale traders to stockpile*	Triggers, Amplifiers	Yes	EU; Member States	Low	Improved resilience to shortage situations	Additional costs of warehousing and management		Regional or national lock-in of critical medicines
Simplified regulatory requirements for emergency imports	Amplifiers	Yes	EU; Member States	Medium	Faster internal compensation of supply disruptions			Undermines regulatory coherence
Field 2: Measures promoting domestic supply								
Increased subsidies to R&D	Roots	No	EU; Member States	Low			Strengthens EU innovation capacities	Disturbance of technology paths
Subsidies to domestic production	Roots	No	EU; Member States	Low	Improved cost competitiveness of domestic supply	Reduced pressure for efficiency improvement		Misallocation of resources (e.g. due to insufficient R&D spending)
Introduce diversification requirements in public procurement	Roots	Yes	EU; Member States	Medium	Positve demand effect on domestic production	Increased procurement costs		
Publicly promoted emergency manufacturing capacities	Roots	Yes	EU; Member States	Medium	Faster internal compensation of supply disruptions	Increased system costs		Misallocation of resources (e.g. due to insufficient R&D spending)

Source: own representation; *: measures included in the Commission's proposal for a pharmaceutical legislation reform (see Section 1.2).

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