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Veröffentlichungsversion / Published Version

Stellungnahme / comment

Zur Verfügung gestellt in Kooperation mit / provided in cooperation with:

Stiftung Wissenschaft und Politik (SWP)

Empfohlene Zitierung / Suggested Citation:

Cimini, F., Bayerlein, M., Villarreal, P. A., & Schwebel, F. (2024). *Exploring new interregional opportunities for pharmaceutical supply chains: the potential of Mercosur countries to advance the EU's Global Health Strategy*. (SWP Comment, 5/2024). Berlin: Stiftung Wissenschaft und Politik -SWP- Deutsches Institut für Internationale Politik und Sicherheit. <https://doi.org/10.18449/2024C05>

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SWP Comment

NO. 5 FEBRUARY 2024

Exploring New Interregional Opportunities for Pharmaceutical Supply Chains

The Potential of Mercosur Countries to Advance the EU's Global Health Strategy

Fernanda Cimini, Michael Bayerlein, Pedro A. Villarreal and Franziska Schwebel

The European Union's (EU) Global Health Strategy calls for open and strategic autonomy in the field of pharmaceuticals, which would lead to the redesign of EU global supply and value chains as well as trade relations. As the EU and Germany are seeking to diversify their trade partners, the Mercosur countries offer latent potential. Mercosur is the name of the South American trade bloc consisting of Argentina, Brazil, Paraguay and Uruguay, with Venezuela's membership currently suspended. The associate states of the bloc are Chile, Peru, Colombia, Ecuador, Guyana and Suriname. Bolivia is currently awaiting final approval to become a full member of the bloc.

In recent years, attention to this interregional relationship has been dominated by the uncertain fate of the EU-Mercosur free trade agreement (FTA), which has yet to be signed. Despite the impasse, the EU and Germany should make the most of this partnership by linking health and trade under the principles of mutual reciprocity and cooperation, in addition to supporting the strengthening of pharmaceutical capacities in Mercosur countries. This can be done without the EU-Mercosur agreement, and instead by providing a framework for an increase in foreign direct investment in the region, with a focus on R&D activities and regulatory cooperation in the area of medical products. For this to happen, the EU has to facilitate the build-up of new capacities in Mercosur countries for poten-

tial diversification, even if it might come at the cost of its own production capacities.

The EU is engaged in implementing a new Global Health Strategy and reducing import dependencies in the field of pharmaceuticals. Since the outbreak of the Covid-19 pandemic, the world has faced critical medicine shortages, and no EU Member State has remained unscathed. Through the Health Emergency Preparedness and Response Authority (HERA), established in 2021, the EU aims to strengthen its "open strategic autonomy", which includes the identification of dependencies, the development of strategies to overcome them and the incorporation of these strategies into global health governance. In this vein, the European Medicines Agency (EMA) has recently published a list with more



than 300 critical medicines, including basic antibiotics and painkillers such as paracetamol and vaccines against measles, hepatitis B, among other things. As a result, the calls for diversifying trade and friend-shoring (i.e. reallocation of production to trusted countries) have gained relevance. The economic implications of the EU's new approach to securing the availability of medicines within EU Member States are still not clear and are being addressed by an increasing number of initiatives. The Global Health Strategy, however, already touches upon important pillars of the commercial agenda, such as access to medicines, intellectual property (IP) rights and government procurement. It also carries important geopolitical implications, since it calls for a reassessment of the EU's relations with the world's largest suppliers of medical commodities – China and India – and the construction of new relationships.

In view of the increased strategic relevance of Latin America for EU foreign affairs – expressed at the high-level Community of Latin American and Caribbean States (CELAC)-EU summit held in July 2023 – and of the EU-Mercosur FTA, which has yet to be signed, the challenges and opportunities of this bilateral trade relationship for global health policy and pharmaceutical supply chains have to be explored. Health and trade should be linked under the principles of mutual reciprocity and cooperation.

EU-Mercosur relations in the field of pharmaceuticals

The comparative advantages of the EU in the field of pharmaceuticals, as compared to Latin America and the Caribbean, have historically been asymmetrical. Whereas the EU is the world's largest exporter of pharmaceutical products, Latin American countries account for only 1 per cent of global exports.

The EU as a whole is also the main source of goods to and foreign direct investments in Latin America. Between 2003 and 2021, the value of foreign direct investment an-

nounced by EU companies accounted for 50 per cent of all announcements in the region. Additionally, Latin America has been an important market for the EU, with EU companies leading in sales in the region: Among the top 20 transnational corporations, 60 per cent of all sales were from EU companies.

A similar trade pattern emerges when focussing on the EU-Mercosur trade in pharmaceutical goods. Mercosur can be considered as an economically strong subset of Latin American countries, which makes the bloc particularly interesting for trade relations with the EU. The EU accounts for almost 50 per cent of imports into the Mercosur market (see Figure).

In terms of the active pharmaceutical ingredients (API) necessary to produce finished pharmaceutical products, the EU is the second-largest supplier after China and has a 20 per cent share, followed by India with 14 per cent. The share of Mercosur API exports to the EU is slightly higher than of pharmaceutical goods, comprising 0.06 per cent and 0.04 per cent of the EU's total volume, respectively. Nonetheless, the share is remarkably low (see Figure).

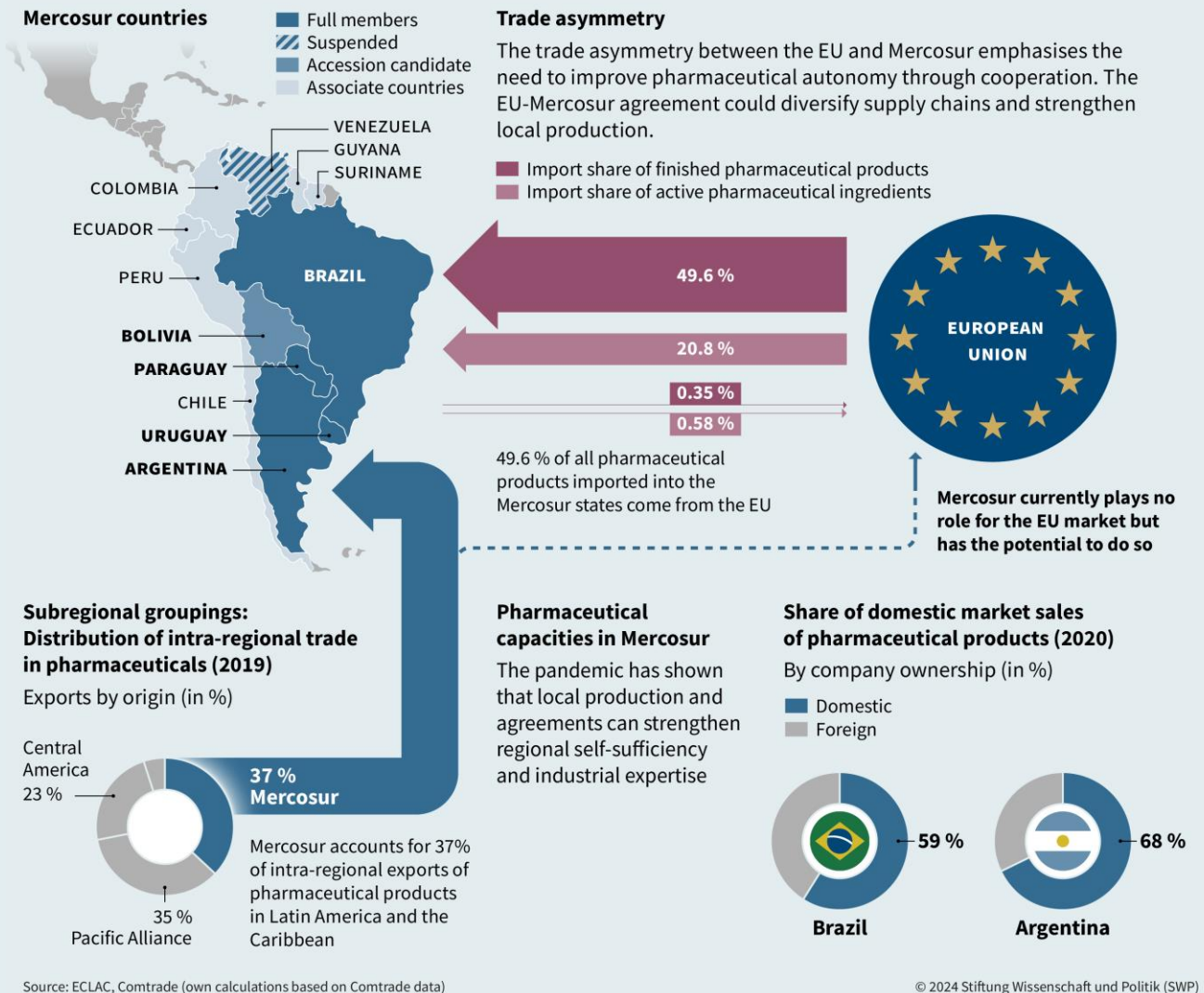
Highlighting pharmaceutical capacities in Mercosur

Despite the long journey ahead to achieve a comparative advantage in the pharmaceutical global market, the Mercosur countries are on their way to strengthening the health economic-industrial complex. When considering the Latin American region, the participation of Mercosur stands out with a 37 per cent market share (see Figure), as this grouping includes two of the region's largest pharmaceutical exporters, Brazil and Argentina. These two countries also account for three-quarters of all regional exports of APIs from Latin America and the Caribbean. However, the relevance of Mercosur goes beyond economic powerhouses such as Argentina and Brazil, but also encompasses Paraguay and Uruguay, which are also expanding their pharmaceutical industries' capabilities.

Figure

EU-Mercosur relations in the pharmaceutical sector

Illustration of inter- and intra-regional trade in pharmaceutical goods and the potential for further cooperation between Mercosur and the EU



Although Mercosur countries already harbour capacities, there is important potential for growth. The share of market sales by domestic companies is 68 per cent in Argentina, 59 per cent in Brazil (see Figure). Brazil already counts 43 manufacturing sites, but only 13 hold an approval from the EMA. Nonetheless, Brazil's pharmaceutical market has grown steadily with the increasing local demand for pharmaceuticals, which triggered the decision to strengthen regional production by national companies through targeted policies, such as tax breaks,

that would create a favourable market. This also offers a diversification potential for the EU, especially since manufacturing sites usually operate under the Good Manufacturing Practices model, which is essential for ensuring the quality of products.

A similarly strong market can be found in Argentina, even considering the difficult state of the nation's economy, with several domestic companies producing specialised APIs as well as biosimilars. Although Brazil and Argentina are generally considered the most important sites for pharmaceutical

innovation and production, the EU should also focus on Uruguay and Paraguay, as both countries hold considerable capacities and currently mostly supply domestic markets.

Uruguay's pharmaceutical industry – which is especially driven by multinational companies joined within the Uruguay Pharma HUB Group – supplies a considerable 42 per cent of its domestic market. Simultaneously, Uruguay – jointly with Argentina, Brazil and Colombia – accounts for most pharmaceutical exports to South America. Relative to its population, Uruguay is a strong actor in the pharmaceutical production and R&D sector, having numerous synthetic and biological products in the pipeline. Additionally, Uruguay provides a comparably stable economy and political landscape.

Lastly, the pharmaceutical industry in Paraguay is ever-growing and attracting companies from neighbouring countries, particularly from Argentina. For more than 10 years now, several local pharma companies have been following the Good Manufacturing Practices. The pharma market for over-the-counter products is steadily rising in the country, creating opportunities for cooperation.

The most recent examples illustrating the significance of the pharmaceutical capacities of Mercosur countries are the efforts made during the Covid-19 pandemic. On 27 June 2020 the Brazilian government announced that it had entered into an agreement with the United Kingdom to produce AstraZeneca's vaccine locally. Similarly, Brazil's Instituto Butantan entered a cooperation with the Chinese Sinovac Life Sciences to produce vaccines. BioNTech and Pfizer announced on 26 August 2021 that they would outsource manufacturing to Eurofarma in São Paulo.

In Argentina, AstraZeneca entered a technology transfer agreement with mAbxience to produce the API for its vaccine, while the finished doses were manufactured by Liomont in Mexico. Argentina's Laboratorios Richmond started producing components of the Russian SputnikV vaccine while importing the API.

These results were only possible due to long-standing institutional capacities pres-

ent in these countries, and yet there is much to be done. This need for action is also recognised by CELAC, which launched a plan for self-sufficiency in health matters. In this vein, Brazil's Ministry of Health financially supported Fiocruz in becoming a World Health Organization hub for mRNA vaccines. Both plans touch upon issues that are crucial to bilateral trade between the EU and Mercosur.

The trade agreement and beyond

It is not yet possible to say whether the EU and Mercosur countries will be able to overcome the impasse in signing the FTA. If signed in its current form, the agreement could affect the costs, supply, variety and safety of pharmaceutical goods, harming the capacity of local production. Specifically, the implications related to IP rights, government procurement rules and technical regulations deserve a closer look. Irrespective of the agreement being signed, the current provisions highlight the necessary groundwork for increasing interregional cooperation.

Intellectual property rights

The EU-Mercosur draft agreement makes it explicit that public health is a safeguarded policy objective that cannot be limited by the commitments to IP rights under the agreement. Unlike in other EU FTAs, Mercosur countries managed to leave the TRIPS-plus provisions out of the text. These provisions refer to the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights) and usually extent patent life of, for example, pharmaceutical products which are not necessarily innovative. Regarding patenting, this will be the second FTA signed by the EU that does not contain obligations related to the extension of patent life. Also, Mercosur countries have not accepted any additional enforcement mechanisms for the protection of patents than those currently provided by their domestic legislation. Finally, the agree-

ment so far does not incorporate – like other EU FTAs – data exclusivity rules. These provisions allow for the use of data – from clinical tests submitted by an originator company, to health regulatory authorities for the approval of generic pharmaceutical products. Since clinical trials tend to be time-consuming and costly, the absence of these provisions favours the production of generics by Mercosur countries.

Government procurement rules

According to the current version of the FTA, EU companies would participate in tenders for public-sector purchases under the same conditions as local companies. However, as Brazil and Argentina are struggling to develop their national pharmaceutical industries, they allege that this rule would harm domestic production. Both countries have adopted policies to use public budgets to support local production. Under the agreement, these programmes could be questioned by EU partners, restricting the policy space of Mercosur governments.

Technical regulations

The chapter on “technical barriers to trade” (TBT) of the agreement goes beyond the one stipulated by the World Trade Organization, setting “TBT-plus” standards with the incorporation of “good regulatory practices”. In this case, the concerns by Mercosur countries go beyond the wording of the agreement, as these provisions can both protect consumers but also create unnecessary obstacles to trade. In addition, the EU has incorporated the “precautionary principle”, which means that public authorities have a legal right to act to protect human, animal or plant health, or the environment, in the face of a perceived risk, even when scientific analysis is not conclusive. Although these provisions are set to ensure rapid intervention in emergencies related to agriculture and food trade, they might also affect other biocomponents. Besides, the EU has recently changed the course of the negotiations by unilaterally defining new

requirements for deforestation-free supply chains. It is not clear yet how the reform of the EU pharmaceutical legislation will also create new due diligence obligations affecting trade between the two regions.

EU-Mercosur: Challenges and opportunities for healthy trade

Considering the existing pattern of trade and investment as well as the local capacities, the Mercosur region presents an important opportunity for the EU to advance its Global Health Strategy. The region is already an important market for EU companies and has the potential to also become a supplier. The increase in production by Mercosur countries would have many advantages: (i) foster pharmaceutical autonomy in the region, (ii) increase the diversification of pharmaceutical supplies to Europe and the rest of the world and (iii) advance the innovation and launch of new medicines while considering local biodiversity. For that, the EU should collaborate to strengthen the research and production capacities of Mercosur countries through four different pathways: (i) redesign global value chain strategies, with a focus on R&D, (ii) intensify bilateral cooperation as part of the Global Gateway strategy, (iii) enable access to new innovations through flexible IP rules and (iv) support local public procurement.

Redesign supply and value chains

As the EU intends to reorganise its supply and value chains, Mercosur countries offer the potential for new investments, but this will require a new strategic approach from both sides. In 2021, CELAC approved a plan for self-sufficiency in health matters, with the aim to strengthen the pharmaceutical sector by attracting foreign direct investment, facilitating R&D and supporting local production chains.

Under this framework, Mercosur countries are promoting international investment and public–private partnerships to carry out joint projects that could enhance

local capacity. Central to this strategy is the need to foster technology transfer and the integration of regional global value chains. It will be imperative to redesign the three main stages of the pharmaceutical supply chain, which involves R&D, product manufacturing and marketing. Whereas the first stage is mostly concentrated in large pharmaceutical firms in the United States and Europe, the subsequent stages are most frequently outsourced to large-scale production in competitive countries, especially China and India. Therefore, if the EU wants to reduce its dependency on these two suppliers, it will require long-term collaboration between the states and corporations in order to build the capacities of new partners. Until now, most of the foreign direct investments steered to Latin America have targeted production and marketing, while fewer than 1 per cent focus on R&D.

It is urgent to leverage and expand existing innovation capacities to attract quality investments in the pharmaceutical sector so that the region can reduce its external vulnerabilities and potentially become a new source of APIs. The EU can directly support R&D via Horizon Europe with research grants tailored towards promoting inter-regional research cooperation. The potential of research cooperation agreements through co-funding mechanisms in the field of health should be explored further. As part of its activities to build and strengthen partnerships within industry in the field of health, exploring new constellations of EU-Mercosur pharmaceutical supply chains could offer mutual benefits.

However, given the oligopolistic structure of the pharmaceutical sector, the argument for orchestrating the modular reconfiguration of pharmaceutical supply chains should not solely be made based on rising geopolitical tensions that spill over to health issues. Rather, pharmaceutical companies' economic interests are incentive enough to bring these actors on board for opening up new supply and value chains through financial commitments. To support this, the EU and its Member States will have to design new institutions and incentives

to support companies as they aim towards strategic diversification involving technological transfer and capacity-building, including not just knowledge but also human resources and infrastructure.

Strengthen bilateral cooperation

Within the Global Gateway initiative, the EU follows the self-proclaimed aim to foster health care capacities worldwide to combat diseases. One priority area lies in strengthening or developing local production capacities to boost self-sufficiency across the globe. To that end, in 2021 a partnership between CELAC and the EU was founded to support the efforts of enhancing the region's health resilience. The "European Union – Latin America and Caribbean Partnership on local manufacturing of vaccines, medicines and other health technologies, and strengthening health systems resilience" ultimately should also serve the goal of further developing the bond between the EU and the Latin American and Caribbean region. In 2023 the initiative facilitated the exchange between pharmaceutical companies from both regions, with the end goal of attracting investment into the region's sector.

The CELAC plan provides important momentum to help countries in the region develop and evolve their capacities in all stages of pharmaceutical production. Mercosur countries should use the plan as a basis to develop national initiatives and regional agendas to foster the pharmaceutical market across Latin America and the Caribbean. For the EU, the Global Gateway strategy could be a major tool used to advance cooperation with Mercosur countries to develop the regional pharmaceutical market.

So far, much of the existing bilateral cooperation has focussed on environmental protection, especially in the Amazon region. Yet, as the intersection of health and environment has increasingly become politically prominent – for example through the growing importance of concepts such as "One Health" – there is the potential to expand this collaboration to related areas, like biodiversity and even biosecurity.

Recently, Brazil and Germany signed a cooperation agreement for the implementation of the “NB4”, a maximum biological containment laboratory, which will allow for the study of pathogens capable of causing serious diseases with a high degree of transmissibility. Initiatives such as these should be strengthened to expand bilateral cooperation in the field of health.

Enabling new innovations

With Mercosur countries still lagging behind in R&D, fostering access to new technologies and patent information through research cooperation with companies is crucial to the development of the technological capacities in the region. As evidenced by multiple empirical studies, the facilitated and voluntary transfer of technology and patents through new business operations would also have important effects on access to medicines.

The Covid-19 pandemic has substantially provided traction to the debate on a more flexible approach to IP rights. The central question here is whether the potential gains from protecting innovations are outweighed by the need for the rapid production and distribution of vaccines. Irrespective of the answer to this highly contentious question, the debate has opened a critical juncture concerning new framings for fostering the voluntary transfer of technology and facilitating market entry for generics. The production of generic medicines has played an important role in the region in the last decades, providing access to fairly priced drugs.

According to certain projections, the number of drugs with patents set to expire will double in the coming years, offering opportunities for the local manufacturing of existing drugs, including the launch of new formats and dosages. The lower the barriers to the voluntary transfer of technology, the faster the local capacity to increase production, including of APIs. As APIs require large-scale production capacity and generate relatively limited marginal gains, the region could leverage the development of other market segments (such as

generics and quality medicines) to improve the sector’s downstream integration, while developing the production capacity for the complex APIs needed to develop new generation drugs. In this scenario, the EU could take advantage of these opportunities and also create new ones by making certain IP rules more flexible. This would require additional financial incentives for the transfer of technology.

Support local public procurement

Public procurement has been largely used as an instrument to support local production. In Brazil, the Ministry of Health has implemented a specific procurement tool to promote local production called Productive Development Partnerships. Under these partnerships, the Ministry of Health agrees to purchase a product for a fixed term of up to 10 years. In turn, private companies agree to transfer the production technology for this product to a national public laboratory for the same period. During the technology transfer process, private companies supply the product to the health system. This instrument is currently under revision by the Brazilian Federal Court of Auditors. There are many areas for improvement of this instrument, which includes the participation of domestic private laboratories and its connection with the regional supply chain.

Initiatives such as these could be an opportunity for the EU to advance its interests of supply chain diversification and market-opening without harming local production in South America. Through product development partnerships, access to the Mercosur market – under long-term public contracts – would compensate for possible private losses inherent to the transfer of technology. However, the EU-Mercosur agreement could make such “buy national” schemes illegal under the FTA.

Foster regulatory cooperation

Another way in which Mercosur countries and the EU could explore synergies is

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ISSN (Print) 1861-1761
ISSN (Online) 2747-5107
DOI: 10.18449/2024C05

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February 2024

through closer regulatory cooperation in the field of health. This can be done without a need to rely upon the FTA. Instead, closer regulatory cooperation can be achieved through internal reforms in Mercosur countries, legally non-binding agreements between Mercosur and the EU as well as encouraging EU-based companies to invest in Mercosur countries.

One example of internal reforms, following the case of Brazil, is to give special treatment to companies using domestic APIs with accelerated approval regimes. There is, however, no regulatory approval of new medical products at the Mercosur level. Instead, regulatory approval must be made through the national procedures of each country. Therefore, new partnerships between the EU and Mercosur countries could be founded in order to streamline approval processes. Regulatory cooperation of this kind would help reduce the duration and costs involved in new applications, either for wholly new medicinal products or for generics, by way of so-called equivalence procedures. It could be an expansion of the existing confidentiality agreement between the EMA and the Brazilian Health Regulatory Agency, through which both institutions exchange confidential information on medical products that they can later use in their assessments. Deepening this collaboration to include regulatory approvals in both Brazil and the other Mercosur countries could make business decisions more predictable and would lower technical barriers for EU companies.

Such an example of closer regulatory cooperation in the marketing authorisation of medicines would require institutional trust. But it also risks becoming a unilateral exercise. However, there are alternatives for unilateral regulatory cooperation. Instead of fully relying upon the recommendations of the EMA, the exchange of information between the EU and Mercosur in the field of medicines could allow for a faster evaluation

of data submitted for the approval of new medical products, whereas the final approval would lie within each national agency.

Conclusion and recommendations

The opportunities for elevating health on the trade agenda between the EU and Mercosur are manifold, as are the challenges. On the one hand, the Mercosur region offers a valuable opportunity for trade diversification. On the other hand, the market competition facilitated by the agreement will inevitably harm the Mercosur partners, reducing local production. This is a choice that the EU has to make: either to invest in building new capacities in Mercosur countries for potential diversification, or to focus on its own production capacities.

The first scenario would require the EU to create incentives for technological transfer along with foreign investment, including flexible IP rules. In the second scenario, diversification, if considered, would remain under strong IP protection. It is uncertain which pathway the EU is going to choose, as it is currently working on a new pharmaceutical package that has divided public opinion as well as political support on this matter. If the lessons from Covid-19 are to be taken seriously, the first option should be considered: Without changing its approach to trade and investment in the pharmaceutical sector, the EU will not be able to advance its Global Health Strategy. On the contrary, as long as the supply chains remain asymmetrical and highly concentrated in a few companies and countries, there is no guarantee that medication needs will be met, as Covid-19 has shown. Additionally, the EU's goal of open strategic autonomy demands higher levels of trade diversification in vital areas beyond raw materials, for example pharmaceuticals.

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