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THE ROLE OF TRADE AGREEMENTS IN THE IMPORTATION OF MEDICAL SUPPLIES: A COMPARATIVE STUDY OF THE CHINA-ECUADOR FREE TRADE AGREEMENT AND THE MULTILATERAL TRADE AGREEMENT WITH THE EUROPEAN UNION

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Cuenca – Ecuador 2025 I dedicate this work to my parents John and Kathy who have been the pillar and support throughout my life, they have always strived so that I lack nothing in this life and today is the result of their teachings and lessons, which has allowed me to reach this point in my life with all their love and affection.

To my brother Sebastian who, despite the senseless fights, has supported me in his own way, and I hope I can continue to be a guide in his life so that the mistakes I make, he does not make.

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Abstract

This research develops a comparative analysis between two strategically significant trade agreements for Ecuador. The Free Trade Agreement (FTA) with the People's Republic of China, in force since 2024, and the Multipart Trade Agreement with the European Union, effective since 2017. The study focuses on evaluating the specific effects of both instruments on the medical supplies sector, with an emphasis on hypodermic needles as a representative input. It considers variables such as pricing, quality standards, product accessibility, degree of trade dependency, supplier diversification, and technological innovation.

Using a descriptive and comparative methodology based on statistical data, official documents, and technical literature, the study reveals that the FTA with China has led to an immediate reduction in the import costs of medical supplies, facilitating the supply of the Ecuadorian market. In contrast, the Agreement with the European Union has improved access to advanced medical technologies, raising quality standards and strengthening economic integration with European countries, albeit with less visible effects on the prices of medical supplies.

It is concluded that both Agreements offer benefits to Ecuador and ensure access to a wide range of medical supplies. The FTA with China is effective in supplying essential products, while the Multipart Agreement with the EU diversifies supply sources and promotes technological modernization in the health sector. The strategic articulation of both treaties could contribute to strengthening the healthcare system and enabling a more robust and equitable management of medical resources in Ecuador.

Keys Words

China, Ecuador, European Union, Trade Agreement, Medical Supplies.

EL ROL DE LOS ACUERDOS COMERCIALES EN LA IMPORTACIÓN DE INSUMOS MÉDICOS: ESTUDIO COMPARATIVO DEL TRATADO DE LIBRE COMERCIO CHINA-ECUADOR Y EL ACUERDO COMERCIAL MULTIPARTES CON LA UNIÓN EUROPEA

RESUMEN

La presente investigación desarrolla un análisis comparativo entre dos acuerdos comerciales estratégicos para Ecuador: el Tratado de Libre Comercio (TLC) con la República Popular China, vigente desde 2024, y el Acuerdo Multipartes con la Unión Europea, en vigor desde 2017. El estudio se enfoca en los efectos específicos de ambos instrumentos en el sector de insumos médicos, con énfasis en las agujas hipodérmicas, y considera variables como los precios, estándares de calidad, acceso a los productos, grado de dependencia comercial, diversificación de proveedores e innovación tecnológica.

Mediante una metodología descriptiva y comparativa, basada en datos estadísticos, documentos oficiales y literatura técnica, se evidencia que el TLC con China ha generado una reducción inmediata en los precios de insumos médicos, facilitando el abastecimiento del mercado ecuatoriano. Por su parte, el Acuerdo con la Unión Europea ha permitido mejorar el acceso a tecnologías médicas avanzadas, elevando los estándares de calidad y fortaleciendo la integración económica con los países europeos, aunque con efectos no tan visibles en los precios de insumos médicos.

Se concluye que ambos Acuerdos, para Ecuador, ofrecen beneficios y permiten el acceso a un sinnúmero de insumos médicos. El TLC con China es eficaz en el abastecimiento de productos esenciales, mientras que el Acuerdo Multipartes con la UE diversifica las fuentes de suministro y promueve una modernización tecnológica del sector salud. La articulación estratégica de ambos tratados puede contribuir al fortalecimiento del área de salud y a una gestión más sólida y equitativa de los recursos médicos en Ecuador.

Palabras Claves

Acuerdos Comerciales, China, Ecuador, Insumos Médicos, Unión Europea.

THE ROLE OF TRADE AGREEMENTS IN THE IMPORTATION OF MEDICAL SUPPLIES: A COMPARATIVE STUDY OF THE CHINA-ECUADOR FREE TRADE AGREEMENT AND THE MULTILATERAL TRADE AGREEMENT WITH THE EUROPEAN UNION

1. Introduction

We currently live in a globalized society where trade agreements have become fundamental tools for facilitating the exchange of goods and services between countries, promoting economic growth and international cooperation. In the field of health, the importation of medical supplies is a practice that ensures access to medicines, equipment, and technology for healthcare. In this context, trade agreements play an important role by establishing standards reducing tariff and non – tariff barrier, and promoting stability in trade relations. However, their specific impact on the importation of medical supplies varies depending of the characteristics of each agreement and the economic dynamics of the countries involved.

In the last decade, Ecuador has sought to strengthen its commercial capacity through the signing of trade agreements with strategic partners, which has allowed access to a wide range of products—including high-quality medical supplies. Over the past 10 years, key trade agreements have been signed to facilitate trade with major markets. Two of the most significant are the Free Trade Agreement (FTA) with China and the Multipart Trade Agreement with the European Union. These agreements not only reflect the country's commitment to international trade but also establish clear rules for the import and export of essential goods, including those related to the health sector.

Thanks to these treaties, Ecuador can access medical supplies, medications, and equipment under more favorable tariff conditions, reducing costs and facilitating their availability in the local market. Additionally, these agreements establish quality standards and sanitary regulations to ensure that imported products meet high levels of safety and efficacy.

In the case of the FTA with China, the agreement opens the door to the importation of advanced medical equipment and raw materials for the pharmaceutical industry at more competitive prices. On the other hand, the Multipart Agreement with the European Union provides access to state-of-the-art medical technology and high-quality medications from countries with strong health regulations.

This article aims to analyze the role of trade agreements in the importation of medical supplies through a comparative study of the China–Ecuador FTA and the Multipart Agreement with the European Union. This analysis seeks to identify the advantages, challenges, and differences each agreement presents in terms of access to medical inputs, as well as their impact on Ecuador's ability to meet the needs of the health sector. The comparative approach will help understand how trade policies can be used as tools to strengthen health security and ensure the supply of essential medical products. It will also include an analysis of suppliers of certain medical supplies to determine which of the two options is most optimal.

The relevance of this research lies in its contribution to the debate on the relationship between international trade and public health, a topic of particular importance in today's world, marked by challenges such as the COVID-19 pandemic, which revealed the urgent need for efficient and resilient supply chains. By examining the cases of the FTA with China and the Agreement with the European Union, this analysis not only provides empirical evidence on the impact of trade agreements on the importation of medical supplies but also offers recommendations to optimize the acquisition of these products from either Europe or China.

In 2020, the world faced an unprecedented health crisis that severely affected both public health and the global economy. According to Hopkins (2024), approximately 6.8 million people died from the COVID-19 virus. This pandemic forced us to reconsider how to respond to a global emergency, especially in international trade and the health sector. As the BBC (2022) noted, the world was not prepared to face a pandemic of such magnitude. Hospital conditions, healthcare infrastructure, response capacity, and availability of medical supplies proved insufficient in the face of an emergency that caught governments and healthcare systems by surprise.

Ecuador was no exception, experiencing both the health emergency and a 7.8% economic downturn (Banco Central del Ecuador, 2021). The pandemic deeply affected the country, resulting in 36,019 deaths (Ecuavisa, 2023), highlighting Ecuador's lack of preparedness and exposing multiple problems and

deficiencies in public health care such as capacity, lack of resources, and shortage of supplies which exacerbated the pandemic's consequences in the country.

This health crisis exposed the global shortage of resources and medicines, as well as the lack of production capacity. This situation benefitted the pharmaceutical sector, which had to increase its production to meet the rising demand, resulting in greater profits for pharmaceutical companies. These firms capitalized on the spike in demand, especially for medical supplies used to treat respiratory conditions.

The country's mass vaccination campaign significantly reduced COVID-19 infections and helped control the pandemic. However, demand for certain medical products remained steady, creating new opportunities for pharmaceutical companies and medical supply distributors, which saw their revenues increase. A noteworthy example is DIFARE S.A., which rose from tenth to second place in Ecuador's ranking of top-earning companies between 2019 and 2020 (Coba, 2021).

1.1 Objectives

To analyze the role of trade agreements in the importation of medical supplies through a comparative study of the China-Ecuador Free Trade Agreement (FTA) and the Multipart Agreement with the European Union.

Specific Objectives

- 1. To define the current state of medical supply imports in Ecuador.
- 2. To analyze the characteristics of the China-Ecuador Free Trade Agreement with the European Union in the field of medical supplies.
- 3. To conduct a comparative analysis of the effects of both agreements on Ecuador.

1.2 Theoretical framework

To understand how international trade operates, it is essential to grasp several key concepts. Not all of them are strictly related to commerce; it is also necessary to consider other academic areas such as Political Science, Customs Law, Public International Law, and Regional Integration, among others.

The main goal of countries or regional blocs in trade matters is to obtain the greatest possible benefits through the signing of agreements and trade treaties to foster their development. However, there is often one party that benefits more than the other. According to Gazol (2016), free trade is an aspiration that dates back to the first Industrial Revolution. In the works of Smith (1776) and Ricardo (1817), free trade is promoted as a key factor in national development. Although some later authors supported protectionism, neoclassical economists reaffirmed the principles of free trade.

From the mid-20th century onward, the ideas of free trade resurfaced with the birth of the General Agreement on Tariffs and Trade (GATT), which was in force from 1948 to 1994. Over time, several rounds of negotiations were added to GATT. However, due to emerging problems and deficiencies in its rules, the Uruguay Round led to the creation of the World Trade Organization (WTO, 2024).

The World Trade Organization (WTO) is the only international organization that deals with the rules governing trade among nations. Its foundation lies in WTO Agreements, which have been negotiated and signed by most countries engaged in global trade and ratified by their respective parliaments. Its goal is to ensure that trade flows as smoothly, predictably, and freely as possible (WTO, 2024).

The WTO seeks to reduce or eliminate trade barriers through the signing of agreements while ensuring that its rules are followed, acting as a forum for international trade negotiations. While joining the WTO requires countries to gradually liberalize trade with other members, they can also sign additional trade agreements that result in greater degrees or faster rates of trade liberalization between specific partners. According to the WTO, 373 regional trade agreements are in force as of January 2025.

Each country seeks different benefits when signing trade agreements. For some, they are the foundation of strategic alliances; for smaller countries, they offer access to larger markets. Trade agreements worldwide differ in scope and type (Hamanaka, 2020). These agreements may include Free Trade Agreements (FTAs), Preferential Trade Agreements, or Customs Unions. FTAs are mechanisms used by countries to open their markets by eliminating existing trade barriers (Medina, 2020).

Hamanaka (2020) identifies two key stages in FTA negotiations: the initiation and conclusion of the process. To determine success factors, he analyzed 25 rounds of trade negotiations in Singapore. His findings led to three hypotheses, first the presence of diplomatic missions in partner countries facilitates bilateral relations, increasing the likelihood of agreement; second when a country is involved in multiple negotiations, resources are often reallocated from less relevant partners to more strategic ones, complicating consensus; and third negotiations between countries with high and low tariffs are often difficult and frequently suspended.

Additionally, there are economic and statistical factors that increase the likelihood of a successful FTA. These include geographic proximity between trade partners, relative distance from the rest of the world, the size and similarity of their economies, greater capital-to-labor ratio differences between the two countries, and smaller differences in this same ratio among members of the agreement compared to the global average (Baier & Bergstrand, 2004).

Regardless of potential gains or losses, signing FTAs is a common practice since countries often seek abroad what is too costly to produce domestically (Gazol, 2016).

1.2.1 Value chain

The value chain is a concept developed by Michael Porter (1985) that describes the interconnected activities an organization performs to create value in its products or services. According to Porter, the value chain is divided into primary and support activities. Primary activities include inbound logistics, operations, outbound logistics, marketing and sales, and after-sales service. Support activities include firm infrastructure, human resource management, technology development, and procurement (Porter, 1985).

In the context of medical supplies, the value chain spans from the acquisition of raw materials and the manufacturing of supplies to their distribution and delivery to healthcare centers Chopra & Meindl (2016) indicate that the value chain in the healthcare sector is essential to ensure that medical products reach patients efficiently and safely, while maintaining high quality standards.

1.2.2 Suppliers

Suppliers are entities or individuals that provide goods, services, or inputs necessary for the operation of an organization or sector. In the context of medical supplies, suppliers play a crucial role in ensuring the availability of essential products for healthcare delivery. According to Kotler & Keller (2016) suppliers are "key stakeholders in the supply chain, as their performance directly affects an organization's ability to meet its goals."

In the healthcare field, relationships with suppliers are fundamental to ensuring the quality and continuity of medical inputs. As Monczka et al. (2015) point out, "effective supplier management involves not only selecting the most suitable partners, but also building strategic relationships that foster collaboration and continuous improvement."

1.2.3 Hypodermic needles

Hypodermic needles are essential medical instruments used for administering medications, vaccines, and extracting bodily fluids (AdvaCare Pharma, 2025). Modern hypodermic needles are primarily made of stainless steel due to their corrosion resistance and durability. Some may have plastic coatings to facilitate use (UKMEDI, 2023),

These needles consist of a thin, hollow tube, generally made of stainless steel, and are attached to a syringe that allows the injection or aspiration of liquids. According to the World Health Organization (WHO, 2023), hypodermic needles are "essential tools in modern medical practice, used in a variety of procedures from vaccine administration to blood sample extraction."

The design and safety of hypodermic needles have significantly evolved to reduce the risk of needlestick injuries and prevent infections. Safety needles include mechanisms that cover the needle after use, minimizing the risk of exposure to bloodborne pathogens (CDC, 2023). Hypodermic needles are critical medical tools that facilitate treatment administration and diagnostic procedures, significantly contributing to healthcare services.

1.2.4 Tarrif code 9018.31.90

Tariff code 9018.31.90 corresponds to the classification in the Harmonized System (HS Code) for instruments and appliances used in medicine, surgery, dentistry, or veterinary medicine. Specifically, this code refers to:

- Catheters, needles, cannulas, and similar products used in medical procedures.
- These products are typically disposable or single use and are designed for specific applications in the healthcare field.

For the Ecuadorian market, the main exporting countries are Germany, the Netherlands, France, and Spain. The advantage of European products is their high quality and compliance with international standards such as the CE (Conformité Européenne) certification. However, one drawback is that their prices tend to be higher compared to Chinese products. Nevertheless, they offer greater reliability and durability.

On the other hand, China is the world's leading exporter of medical products, including those under tariff code 9018.31.90, due to its large-scale production capacity and competitive costs. The advantage of Chinese products is their affordability, though it is crucial to verify their quality and compliance with international standards. Ecuador has increased its imports from China in recent years due to the strategic trade relationship between the two countries.

According to ARCSA (2024), various medical products must be regulated before importation and subsequent commercialization in the country. This public agency has categorized medical inputs to identify which group a product belongs to.

1.2.5 Definitions:

Medical devices. - These are articles, instruments, apparatuses, devices, or mechanical inventions, including their components, parts, or accessories, manufactured, sold, or recommended for use in diagnosis, curative or palliative treatment, prevention of a disease, disorder or abnormal physical condition or its symptoms, to replace or modify anatomy or a physiological process, or to control it. This includes amalgams, varnishes, sealants, and other similar dental products (ARCSA, 2024).

Medicines.- Any pharmaceutical preparation or dosage form whose formula is expressed in international system units, composed of a substance or mixture of substances with constant weight, volume, and percentages, produced in legally established pharmaceutical laboratories, packaged or labeled for distribution and marketed as effective for diagnosis, treatment, mitigation, or prevention of disease, physical anomalies, or symptoms, or to restore, correct, or modify the balance of organic functions in humans and animals (ARCSA, 2024).

Medicines, biological products, medical devices, biochemical and diagnostic reagents for catastrophic and rare/orphan diseases. - Products intended for the diagnosis, prevention, or treatment of catastrophic and rare/orphan diseases (ARCSA, 2024).

Biochemical reagents. - These are all substances or products used (with or without specialized machines) to react with organic fluids or materials and assist in the diagnosis, monitoring, control, and treatment of human diseases (ARCSA, 2024).

1.2.6 Registration of Imported Medical Devices, Dental Products, and Diagnostic Biochemical Reagents (Foreign Manufacturing)

ARCSA (2024) outlines a series of requirements for the entry of foreign-manufactured medical supplies, medical devices, dental products, and diagnostic biochemical reagents into Ecuador.

Requirements:

• Application submitted through the Ventanilla Única Ecuatoriana (VUE).

Documents required from the applicant:

- **For legal entities:** certificate of legal existence, appointment of legal representative, ID card or passport, and RUC (Unique Taxpayer Registry) copy.
- For natural persons: ID card, passport (if applicable), and RUC copy.

- Valid operating permit issued by the competent health authority.
- List of medical devices to be registered.
- Proof of payment of the corresponding fee.

Documents required from the product owner:

If the applicant is not the product owner, they must present, only once, a valid, duly legalized authorization from the product owner allowing the applicant (natural or legal person) to apply for sanitary registration in Ecuador. This is only waived in case of changes.

Documents required from the manufacturer:

Free sale certificate issued by the health authority or competent legal entity. Good Manufacturing Practice (GMP) certificate issued by the health authority or ISO certification issued by accredited bodies (legalized). If the conditioner is different from the manufacturer, a Good Conditioning Practice (GCP) certificate or ISO certification (legalized) is required.

Technical documentation:

- Product quality and sterility certificates signed by the responsible technicians.
- Product specifications.
- Description of the product's use
- Product stability certificate signed by the technician who conducted the study.
- Interpretation of the batch code, signed by the responsible technician.
- Original label of the product and provisional label formats for the requested group, in Spanish; instruction manual and original brochures from the country of import.
- Scientific literature about the product.

2. Literature Review

2.1 Current situation of medical supply imports

Currently, there is a high demand for imported medical supplies in Ecuador, largely due to recent trade agreements involving the country, such as the Trade Agreement with the European Union and, more recently, the Free Trade Agreement between China and Ecuador. The need to import these products has increased with technological advancements and rising expectations from users in the healthcare sector. As a result, importing such products has become a priority, given that medical supplies are indispensable in the daily practice of healthcare professionals in hospitals, clinics, laboratories, and health centers. Globally, there is a vast range of supplies, and technological developments continue to grow, benefiting patients.

Due to the broad range of existing medical supplies and their classification according to various medical specialties, this analysis focuses on a limited portfolio of general-use instruments applicable to multiple fields of medicine.

As of January 2023, Ecuador had 1,882 companies dedicated to the sale of medical devices. The Ecuadorian Association of Distributors and Importers of Medical Products (ASEDIM), a key player in the sector, includes 37 distributors and 16 multinational companies, representing 58.15% of the import market. Despite the wide variety of medical devices available worldwide, Ecuador lacks access to many healthcare technologies. In 2021, Europe had over 500,000 medical devices available, while Ecuador only had 271,145 registered medical devices as of 2023 (EKOS, 2023).

Approximately 99% of the medical supplies sold in the Ecuadorian market are imported from countries such as the United States, Germany, China, and South Korea. Therefore, importers hold a cost advantage over local distributors. Only 13 low-risk medical devices are manufactured domestically, such as masks, medical clothing, and gauze. For Ecuadorian products to be exported, they must comply with international standards, including Good Manufacturing Practices (GMP) and ISO 13485 certification standards that are not currently met in the country (EKOS, 2023).

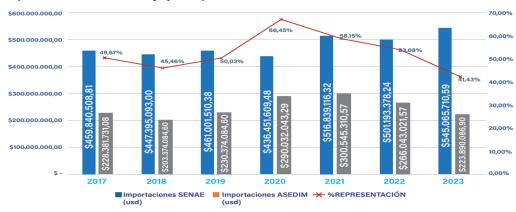
2.2 Imports of medical devices and supplies

Approximately 99% of medical devices in Ecuador are imported. As of February 2024, only 37 of these products were produced domestically. The primary locally manufactured products include disposable surgical clothing, surgical masks, and orthotic devices.

According to Ecuador's National Customs Service (SENAE), medical device imports increased by 8.75% in 2023 equivalent to USD 4 million more than the previous year.

The following chart shows the import data for medical devices and supplies recorded by SENAE from 2017 to 2023:

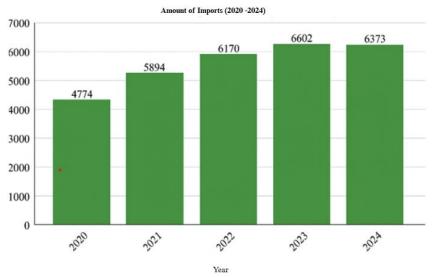
Figure 1
Imports of Medical Devices and Equipment from 2017 to 2023



Note: This figure shows the total value of imported medical supplies between 2017 and 2023.

Source: Asociación de Distribuidores e Importadores de Productos Médicos - ASEDIM. (2024). 2024—Revista Salud en Dispositivos Médicos. [Health in Medical Devices]. [ASEDIM]. ASEDIM. https://drive.google.com/file/d/1WwxUEC70FYKY5q130v6oxU4m106zIMBi/view?usp=drive_link&usp=embed_facebook

Figure 2
Total imports (in metric Tons) of tariff code 9018 from 2020 to 2024.



Note: The graph displays the evolution of total imports in metric tons from 2020 to June 2024. Based on: (Banco Central del Ecuador, 2025)

The graph helps visualize how imports have varied in terms of volume. An increase may indicate higher domestic demand or reduced local production, while a decrease could be associated with tariff policies, economic fluctuations, import substitution, or global logistics changes.

2.3 Trade relations between Ecuador and the European Union

The trade relationship between the European Union (EU) and Ecuador plays a fundamental role in the country's economic development. Since the Trade Agreement entered into force in 2017, bilateral trade has increased by 40%, according to the Delegation of the European Union in Ecuador (EEAS, 2024), generating a significant trade surplus for the Andean country over €8 billion between 2017 and 2023.

Ecuador's preferential access to the EU market since 2017 has been highly advantageous, especially compared to other regional countries such as Peru and Colombia. Ecuador has successfully positioned itself as a major supplier of bananas and organic products. The country's main exports include bananas, shrimp, tuna, roses, cocoa, and coffee.

The EEAS (2024) indicates that the European Union is Ecuador's third most important export destination. However, in the first four months of 2024, exports to the EU grew by 21%, placing it in second position.

Despite strong trade relations with the EU, foreign direct investment remains low, representing less than 1% of Ecuador's GDP, according to the EEAS (2024). This presents a major challenge, as sustained economic development requires increased foreign investment.

This Agreement has been particularly beneficial for Ecuador by reducing tariffs and simplifying import processes, which enables local companies to import high-quality, advanced medical supplies. Moreover, the EU is considered a reliable source of health-safe products an essential factor for Ecuador, especially during emergencies such as the COVID-19 pandemic and within the country's current social and health context.

2.4 The Role of the China–Ecuador Free Trade Agreement in the Importation of Medical Supplies and Devices

The Free Trade Agreement (FTA) between China and Ecuador, which came into effect on May 1, 2024, represents a significant advancement in trade relations between the two countries particularly in the field of medical supplies and devices. This Agreement seeks to reduce tariff barriers and improve Ecuador's access to Chinese products, especially those from China's globally dominant medical manufacturing sector.

According to Sánchez (2024), between January and November 2024, Ecuador's imports from China reached USD 4.747 billion. A technical report from the Ministry of Production, Foreign Trade, Investment and Fisheries (MPCEIP), released when negotiations began in March 2022, estimated that imports from China could grow by 19% as a result of the FTA. Since the Agreement came into effect, over 4,600 Chinese products have entered Ecuador duty-free. These include industrial inputs such as seeds, fertilizers, chemicals, tractors, medical supplies, medications, and vaccines. Consumer goods like digital cameras, hard drives, bicycles, and electric motorcycles have also benefited. Although cell phones were already duty-free regardless of origin, they are included on the list.

One of the FTA's main objectives is to ensure more affordable and efficient access to essential medical supplies by facilitating their importation at competitive prices. According to Sánchez (2024), the elimination of tariffs on medical devices could reduce import costs by up to 20%, which is expected to lower prices for hospitals and healthcare centers in Ecuador. This is particularly important in the context of the COVID-19 pandemic, which exposed the vulnerabilities of health systems due to shortages in personal protective equipment, diagnostic tests, and other essential supplies (Gamba et al., 2022). In this regard, the FTA helps ensure a more resilient Ecuadorian healthcare system in future health emergencies.

However, it is also necessary to assess whether the reduction in costs translates into more equitable access across all regions of the country. As (Martínez, 2022) notes, Ecuador faces significant logistical challenges, particularly in rural areas, which may limit the benefits of the FTA unless accompanied by improvements in product distribution. Therefore, the implementation of the FTA should be complemented by domestic policies to strengthen Ecuador's logistical and distribution infrastructure to guarantee widespread access to imported medical supplies.

Another relevant issue is the sustainability of the medical supply chain. Although the FTA facilitates the importation of Chinese medical devices, it also poses risks of overdependence on a single supplier. The WTO (2023) warns that excessive reliance on imports can leave countries vulnerable to disruptions in global supply chains, as seen during the early stages of the pandemic. To mitigate this risk, Ecuador must diversify its supplier base and avoid relying solely on China, even under the framework of the FTA.

Finally, the FTA presents a major challenge for Ecuador's domestic medical supply industry, which faces significant competition from low-cost Chinese products. Sánchez (2024) notes that tariff elimination could harm local producers, who may be unable to compete on equal footing. This situation could result in greater dependence on imports and reduced opportunities for growth in Ecuador's domestic industry.

To counter this, the Ecuadorian government could implement policies to support the local industry, such as tax incentives, subsidies, and technology transfer programs, which would help domestic companies improve their competitiveness. According to the WHO (2021), policies that support local production can strengthen

healthcare systems and reduce dependence on foreign markets, while also generating local economic benefits. In this way, the FTA could become an opportunity to promote innovation in Ecuador's medical device industry rather than a threat to it.

3. Methods

The methodology employed in this research follows a qualitative approach, supported by rigorous triangulation of data using the following methodological tools:

- 1. Literature Review
- 2. Comparative Analysis

The **literature review** focused on collecting and analyzing academic, legal, and technical information related to the importation of medical supplies, the relevant trade agreements (such as the China–Ecuador FTA and the Multipart Agreement with the European Union), and their impact on the accessibility and efficiency of foreign trade. For this purpose, secondary sources such as scientific articles, reports from international organizations, legal regulations, trade databases, and government publications were consulted.

This methodological tool enabled the identification of trends, gaps, and best practices in the management of medical supply trade. Additionally, it provided a strong theoretical foundation for the **comparative analysis**. According to Creswell (2022), a literature review is fundamental to contextualize the research problem and establish the study's relevance.

The **comparative analysis** was used to evaluate differences and similarities in the implementation of trade agreements between Ecuador and other countries with similar trade characteristics. This method allowed the identification of the specific impacts of the agreements on trade barriers, import costs, and supplier diversification.

Indicators such as tariff rates, import times, quality standards, and availability of medical supplies were analyzed using data from international organizations such as the World Trade Organization (WTO), the World Bank, and databases like OEC (Observatory of Economic Complexity). According to Yin (2018), comparative analysis is an effective tool for contrasting cases and generating relevant findings in qualitative research.

To ensure the validity and reliability of the findings, data triangulation was applied by combining information obtained from both methodological tools. This process allowed for the cross-verification of perspectives and reduced potential bias, which, as stated by (Patton, 2014), strengthens the robustness of qualitative studies. Triangulation ensures that results are consistent and provide a comprehensive view of the impact of trade agreements on the importation of medical supplies in Ecuador.

4. Results

4.1 Comparison between both agreements

Both the Free Trade Agreement (FTA) with China and the Multipart Trade Agreement with the European Union provide preferential access for medical supplies by reducing or eliminating tariffs and facilitating the importation process. In the case of the Agreement with China (in force since 2024), over 4,600 Chinese products entered Ecuador with a 0% tariff immediately, including many medical supplies and industrial raw materials (Gonzáles, 2025).

Meanwhile, the Agreement with the EU (effective since 2017) ensured the immediate removal of tariffs on 100% of Ecuador's industrial exports, including medical equipment and supplies, and established a phased tariff elimination for imports from Europe (EEAS, 2017b). This allowed European medicines, vaccines, and medical equipment to enter with zero tariffs from the beginning, lowering costs and increasing the availability of high-quality medical technology.

Despite these trade benefits, a key concern is the increased competition posed by Chinese imports to Ecuador's domestic medical supply industry. With reduced tariffs, low-cost foreign products especially from China can displace local manufacturers of basic medical goods, such as syringes, lab equipment, or generic drugs. To protect local industry, Ecuador negotiated longer tariff phase-outs for sensitive items from China. For example, medical syringes, which had an 8% tariff, will only reach 0% by 2029 (MPCEIP, 2024).

In comparison, the EU Agreement faced fewer challenges in medical supply imports, since Ecuador does not have a strong domestic base for high-tech medical equipment production. However, there were

concerns regarding dependency on imported drugs and intellectual property rights. In contrast, the China FTA includes a gradual tariff phase-out and offers more protection to national industry.

A major difference between the two agreements is their regulatory scope and policy disciplines. The EU agreement is broader, with rules on standards, competition, and sustainable development, including commitments to labor rights, environmental norms, and regulatory cooperation. The China FTA focuses mainly on trade liberalization. In terms of market access, the EU has offered tariff-free access for virtually all Ecuadorian medical supplies since 2017, though Ecuador exports very few such products to Europe. China also granted duty-free access to most goods, with exceptions or timeframes for sensitive sectors.

The EU agreement includes provisions for public procurement and recognition of international standards, making it easier for domestic companies to supply medical equipment in Ecuadorian hospital tenders. The China FTA, by contrast, does not delve deeply into public procurement or intellectual property disciplines. Its strength lies in market access up to 90% of bilateral goods are duty-free boosting Ecuador's export opportunities in various sectors (Chuquimarca, 2024).

4.2 Impact on tariffs, health regulations, and market access

Both agreements have significantly reduced or eliminated tariffs on medical supplies imported into Ecuador. Following the implementation of the Multipart Agreement with the EU in January 2017, Ecuador set the tariff at 0% for thousands of European medical supplies and capital goods (Mosquera, 2016), Before that, about 8% of imports from the EU still faced tariffs on products such as medicines, vaccines, and medical equipment, but these were either fully or partially removed upon the Agreement's entry into force. Notably, medical equipment and vaccines from Europe, which previously had low tariffs (5% or less), immediately became duty-free, lowering import costs.

In the case of the China FTA, Ecuador agreed to immediately eliminate tariffs on most medical supplies: products such as medicines, which previously faced tariffs of 4% to 10%, now enter duty-free (Gonzáles, 2025). This brings Chinese products on par with European pharmaceuticals in terms of trade conditions.

Many Chinese medical devices such as diagnostic equipment and monitors previously benefited from Most-Favored Nation (MFN) tariffs ranging from 0% to 5%, which were immediately eliminated. For example, ultrasound machines (with 2–3% tariffs) became duty-free as soon as the FTA took effect, facilitating easier access to medical equipment.

4.2.1 Health regulations

Both agreements address sanitary and technical requirements. Ecuador maintains a mandatory sanitary registration for imported medicines and medical devices, overseen by the National Agency for Health Regulation, Control and Surveillance (ARCSA), regardless of the country of origin. Neither agreement removes these controls, as they are crucial for ensuring the safety and efficacy of medical products.

However, the EU Agreement includes chapters on cooperation regarding Technical Barriers to Trade and Sanitary and Phytosanitary Measures (SPS), which promote the harmonization of standards and mutual recognition of certifications (European Commission, 2017). In practice, this means that Ecuador and the EU can work toward accepting each other's conformity assessments such as quality certificates or clinical trials—thus avoiding the entry of counterfeit products. As a result, European CE-marked medical devices face fewer regulatory hurdles in Ecuador, and vice versa, provided equivalent levels of protection are maintained. The EU also simplified labeling requirements for imported products, allowing international pictograms and eliminating unnecessary regulations that raised import costs (European Commission, 2017).

The China FTA also includes an SPS chapter and establishes a bilateral SPS Committee (Article 7.11), which allows China's sanitary measures to be accepted as equivalent, provided China can demonstrate that they meet Ecuador's required protection standards. This facilitates the acceptance of Chinese GMP (Good Manufacturing Practice) or pharmaceutical quality certificates, as long as they align with Ecuadorian standards. However, in practice, regulatory alignment with China may be slower than with the EU, as European norms are generally closer to international standards.

One distinguishing aspect is intellectual property: the EU–Ecuador Agreement incorporates obligations aligned with the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights). For example, it protects European geographical indications and possibly test data for pharmaceuticals, which has raised concerns over the impact on patented drug prices (CDES, 2017). The China FTA does not emphasize these issues, instead focusing on traditional medicine and other areas without altering existing patent rules.

4.3 Medical inputs with tariff reductions

Both agreements have led to tariff reductions in specific categories of medical products:

Medicines and vaccines: Under the China FTA, several finished medicines that previously faced tariffs of 5%–10% now enter duty-free (Gonzáles, 2025).

For instance, antibiotics, analgesics, and drugs for chronic diseases manufactured in China now cost less in Ecuador. Similarly, the EU Agreement has allowed duty-free entry of human-use vaccines (previously at 3%). Vaccines from Europe for influenza, pneumococcus, and HPV now enter freely, easing their procurement by Ecuador's public health system.

Medical devices and equipment: Many diagnostic and treatment devices have become cheaper. With China, items such as electrocardiographs, patient monitors, ultrasound machines, and MRI scanners (previously with tariffs of 0% to 5%) are now duty-free. For example, a Chinese portable ultrasound device that had a 2.6% tariff is now exempt, lowering costs for clinics and doctors. Similarly, the EU Agreement has benefited X-ray machines, CT scanners, incubators, surgical instruments, and high-tech medical machinery, which were classified as capital goods with immediate tariff elimination.

Hospital and laboratory supplies: Everyday healthcare inputs have also been included. From the EU, chemical reagents, base pharmaceutical products, and disposable medical materials are among the tariff exempt items. This includes sutures, wound care materials, gloves, and disposable medical clothing. In the China FTA, items such as needles and catheters (formerly at 4% tariff) now enter duty-free, making Chinese products like infusion sets and low-cost hypodermic needles easier to import.

These tariff reductions have positively impacted the availability and cost of these inputs in Ecuador. Lower import costs allow local distributors to offer medicines and equipment at more competitive prices. The Ministry of Health can now access European vaccines without tariff surcharges, optimizing its immunization campaign budget. During the COVID-19 pandemic, critical supplies (e.g., masks, PPE, ventilators) from China and Europe entered the country at lower costs or with customs facilitations, helping to prevent shortages.

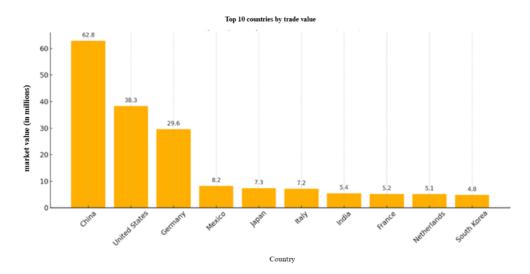
Many pharmaceutical products were liberalized immediately when the EU Agreement entered into force on January 1, 2017. However, some products remained under a gradual tariff elimination scheme of 5 to 10 years, including bandages, cotton, sterile adhesives, and a range of oncology and HIV treatments (EEAS, 2017).

4.4 Data on medical supply and device imports

Ecuador's imports of medical supplies have increased in recent years, partially driven by the trade facilitation provided by these agreements. In 2023, Ecuador imported approximately USD 215 million in medical instruments and devices (OEC, 2024). This representing a 20% increase compared to 2022. China has emerged as the main supplier in this sector, accounting for about USD 63 million (29% of the total) in medical device imports to Ecuador in 2023 (OEC, 2024).

The European Union is also a significant player. Germany exported approximately USD 29.6 million in medical equipment to Ecuador, ranking as the third-largest source, followed by other European countries such as the Netherlands, Italy, and Spain in smaller volumes (OEC, 2024). With the implementation of the FTA with China, some of these competitors may be partially displaced in basic medical technology segments due to China's pricing advantage, potentially affecting the EU's and others' market shares in the coming years.

Figure 3Where does Ecuador import medical instruments from?



Note: The chart shows the main countries from which Ecuador imports medical products.

Based on: OEC. (2024). *Medical Instruments in Ecuador* [Statistics]. The Observatory of Economic Complexity Medical Instruments in Ecuador. https://oec.world/en/profile/bilateral-product/medical-instruments/reporter/ecu.

In the case of medicines and pharmaceuticals, the import market is even larger. In 2023 alone, Ecuador imported USD 861 million in finished medicines. The main suppliers were traditional partners: Colombia (USD 142 million) and Mexico (USD 90 million), followed by Argentina (USD 67 million) and India (USD 66 million) (OEC, 2024).

Among EU countries, Germany led with USD 65 million in pharmaceutical exports to Ecuador, followed by Spain, France, and Italy (OEC, 2024). While China is a global leader in active pharmaceutical ingredients (APIs), it still has a smaller share in Ecuador's finished medicine market and was not among the top five suppliers. However, the FTA could open the door for more Chinese generic or traditional medicines in the future. It is worth noting that Ecuador already imported 92% of its products from the EU tariff-free before 2017; the Agreement further consolidated and expanded this access (EEAS, 2017).

Since implementation, imports from the EU have increased in sectors that benefited from the agreement. For instance, purchases of European medical machinery and pharmaceutical products grew, with pharmaceuticals becoming the second most imported category from the EU into Ecuador. Between 2005 and 2016 prior to the Agreement imports from the EU had already increased by 86% in value, largely driven by machinery and pharmaceuticals. The Agreement helped ensure those flows continued without facing new trade barriers (EEAS, 2024).

Since the EU Agreement entered into force in 2017, trade in medical goods has shown a moderate upward trend. Ecuadorian companies have taken advantage of high-quality European supplies at lower costs, which is reflected in a rise in imported medical, optical, and technical equipment this category grew by 13.7% from 2022 to 2023, the highest increase among import categories that year (Tendata, 2024).

As for China, the FTA is very recent. Even before it came into effect, China had become the leading supplier of certain items, such as basic medical devices and sanitary protection products. It is expected that thanks to the Agreement, imports from China will increase by an additional 15% in the first year of implementation and will accumulate a 16.3% increase by 2035 (Gonzáles, 2025).

4.5 Trade between China and Ecuador

4.5.1 Advantages of importing from China

According to the Cámara de Comercio Ecuador Shanghái China (2025), international trade with China continues to be a strategic opportunity for businesses of all sizes around the world. In 2025, importing from this Asian giant is more relevant than ever for four main reasons:

1. Product variety and customization

China remains the world's leading manufacturing hub, offering an unparalleled diversity of products. From advanced technology to textiles and machinery, virtually every product category is available with multiple options for quality and price. Additionally, Chinese manufacturers are experts in customizing products to meet each customer's specifications, allowing importers to differentiate themselves in their local markets (Cámara de Comercio Ecuador Shanghái China, 2025).

2. Competitive costs and efficiency

Despite changes in the global economy, China continues to offer highly competitive prices due to its large-scale production, optimized supply chains, and a strong focus on technological innovation. Importing from China remains one of the most cost-effective strategies for reducing expenses and maximizing profit margins (Cámara de Comercio Ecuador Shanghái China, 2025).

3. Improved Logistics Infrastructure

Improvements in logistics infrastructure and trade digitalization have simplified the import process from China. With world-class ports, modern customs systems, and real-time tracking platforms, both maritime and air transportation are now faster and more secure than ever. Additionally, access to shared shipping services makes it possible to import even in small volumes without sacrificing profitability (Cámara de Comercio Ecuador Shanghái China, 2025).

4. Greater trade openness through strategic agreements

In 2025, trade agreements like the Ecuador–China Free Trade Agreement significantly reduce tariffs on many products. This not only makes goods more accessible but also promotes bilateral trade growth, benefiting both importers and final consumers.

Importing from China in 2025 is a strategic decision that can transform how businesses operate. The combination of product variety, competitive pricing, advanced logistics, and an increasingly open trade environment offers unique opportunities for entrepreneurs aiming to grow in the global market (Cámara de Comercio Ecuador Shanghái China, 2025).

4.5.2 Route between Chancay and Guayaquil

The route will connect the Port of Guayaquil with Shanghai via the Peruvian port of Chancay. On February 21, 2025, a new commercial route to China was inaugurated, with a journey time of 27 days, aiming to boost exports between the two countries. This route has been in effect since late 2024 (Infolib, 2025).

The route is operated by the Chinese shipping company Cosco Shipping, which manages the Port of Chancay and expects that Ecuador's incorporation into the route will mark a milestone in the construction of trade networks throughout Latin America. For Cosco Shipping, it represents a major step in its global expansion strategy.

Over the next three years, the Port of Guayaquil will be an additional stop on the WSA5 route, which will reach Chancay from the north of the continent, passing through the Colombian port of Buenaventura. According to Weidong, this integration "will strengthen regional connectivity and provide new momentum for the continent's economic development."

According to Javier Lanza (2025), Executive Director of Contecon the company managing the Port of Guayaquil stated that prior to this new route, shipments from Ecuador to China by sea took between 35 and 55 days, as they had to pass through other ports in the northern region. China, which led the construction of the Port of Chancay (located about 78 kilometers north of Lima), invested approximately USD 1.4 billion in the first phase of the project, completed in late 2024. In 2022, China overtook the United States as Ecuador's main non-oil trading partner (Infolib, 2025).

Figure 4WSA5 Maritime route of COSCO Shipping



Note: The Guayaquil—Chancay—Shanghai route will connect the Port of Guayaquil to the Asia-Pacific region in a 27-day journey, creating a trade bridge between Ecuador, Peru, and China.

Source: Primicias. (2025). La ruta marítima WSA5 de la naviera china Cosco Shipping [The WSA5 Maritime route of the Chinese shipping company Cosco Shipping] Created with Datawrapper [Big Data]. Datawrapper. https://datawrapper.dwcdn.net/ckoCW/1/

The impact of this route on port operations is highly significant, especially for the Port of Guayaquil. The alliance with Cosco Shipping and the launch of this new route have revitalized the port's operations, allowing it to recover and increase the volume of cargo handled by Contecon. With the opening of this trade link between Asia and South America, it is expected that the container capacity in twenty-foot equivalent units (TEUs) will double compared to previous years (AméricaEconomia, 2025).

4.6 Hypodermic needle suppliers

4.6.1 Suppliers in the European Union

Several hypodermic needle suppliers can be found across Europe. One of the main advantages of these suppliers is that their products comply with European certifications and standards required for commercialization within the EU. This represents a significant benefit when importing to Ecuador, as the products already meet ARCSA's regulatory requirements for customs clearance.

Terumo Europe offers hypodermic needles designed to ensure high levels of care and patient comfort. These needles feature a lancet-type sharp tip and a silicone coating to facilitate insertion and minimize trauma. Another supplier is Helmed Bulgaria, which manufactures hypodermic needles compatible with Luer Lock and Luer Slip connectors, available in sizes from 18G to 30G. They are made of stainless steel and are intended for single use. A third option is GBUK Vascular, a provider of a wide range of essential needles and syringes, including both safety and non-safety hypodermic needles, as well as Luer Lock and Luer Slip syringes.

4.6.2 Suppliers in China

China offers an extensive range of suppliers for virtually every type of product—including hypodermic needles. These can be sourced both physically and virtually. Two key platforms that enable direct communication with suppliers are Alibaba and Made-in-China.

Alibaba, a major global platform, connects international buyers with more than 200 Chinese manufacturers of hypodermic needles, offering a wide variety of products and specifications. Made-in-China also features a large list of Chinese hypodermic needle manufacturers, including companies such as Changzhou Longli Medical Technology Co., Ltd. and Northern Jincheng Medic Co., Ltd. Notably, some of these companies supply multinational brands such as Nipro, demonstrating their production capacity and international reach.

5. Discussion

Both trade agreements have played a key role in the importation of medical supplies. Ecuadorian importers and distributors have benefited in several aspects, such as better prices, improved product quality, and expanded market access. These factors have made both the Chinese and European markets attractive for Ecuadorian entrepreneurs and businesspeople aiming to enter or strengthen their presence in the health sector.

Table 1 *Comparative table between the Ecuador – China FTA and the Ecuador – EU Trade Agreement.*

Aspect	China – Ecuador FTA	Ecuador – EU Agreement	Statical comparison of both Agreements
Prices	Immediate tariff elimination (5% - 0%) on medical inputs. Chinese products have lower unit prices.	Reduction in purchase costs for European products (which start at higher base prices)	The FTA reduced import prices by 15%–20%. Chinese unit prices are 30%–50% lower than those of the EU, which are 30%–40% more expensive at the base.
Quality	Wide range of quality. Low-cost Chinese products meet basic standards; ARCSA enforces stricter controls due to high import volume.	High EU standards. Products come with European certifications and are widely recognized for quality. Lower regulatory concern.	About 55% of Chinese products meet ARCSA standards. About 95% of EU inputs carry CE, ISO, or EMEA certifications.
Market access	Greater access to affordable medical supplies from China (no tariff barriers).	Access to European medical technology with a stronger global reputation.	Tariff reductions have been equitable. China represents 62% of Ecuador's medical supply imports, while the EU represents 15%.
Trade dependency	High risk of dependency on one main supplier. China has steadily increased its market share since before the pandemic.	EU offers diversity as a bloc, with different countries specializing in specific medical products.	China's 62% share indicates high dependency, whereas the EU's lower share is more distributed across 27 member countries.
Supplier Diversification	A vast number of Chinese suppliers can meet a variety of needs and standards.	Fewer suppliers in Europe due to strict internal regulations.	China has around 22,000 hypodermic needle suppliers; the EU has fewer due to higher operating costs and consolidation.
Innovation	Innovation is present across Chinese medical products due to its role as a commercial and R&D hub.	Innovation is also strong in the EU, though associated with higher prices and less accessibility.	Approximately 38% of Chinese products are patented more accessible, though basic. Around 72% of EU products are patented higher cost, limited access.

Thanks to these two strategic trade agreements, Ecuador has gained multiple benefits in terms of cooperation, development, and trade. Both treaties have significantly influenced the medical supply sector, including devices, equipment, and healthcare-related materials. In the coming years, Ecuador is expected to adopt a more liberal stance in its trade policy, promoting a freer flow of imports and exports.

It is crucial to understand what each agreement offers and to determine which is best suited for specific needs when importing medical supplies. Additionally, importers must comply with ARCSA's requirements and permits, such as the sanitary registration, which costs around USD 1,200 and is valid for five years. This permit is essential for customs clearance, without it, goods cannot legally enter the country.

Due to these bureaucratic procedures, many people are discouraged from pursuing this business opportunity. However, with patience and effective resource management, the investment can be profitable. That's why this analysis examined the most relevant aspects of medical supply importation under the provisions of both trade agreements.

Price was identified as the most decisive factor for importation decisions in Ecuador, as it has a direct impact on business profitability. In the medium and long term, quality and supplier diversification are also important. But in the current market context, price is the dominant consideration.

5.1 Impact on medical supply prices

The China–Ecuador FTA has had an immediate effect on reducing prices for medical supplies imported from China. After the agreement entered into force (May 2024), 4,677 Chinese product subcategories became tariff-free, including medical supplies, vaccines, and pharmaceuticals (Silva, 2024). Before the FTA, products like hypodermic needles faced a 5% tariff; now, they enter with a 0% tariff, lowering costs in the Ecuadorian market.

Given that Chinese products already competed on price, the removal of tariffs further strengthened their affordability. In practice, hospitals and local distributors can now purchase needles, disposable syringes, and other basic supplies at even lower costs than before. This reduction in costs benefits both public and private healthcare systems by lowering procurement expenses and improving opportunities for business growth in the health sector.

The EU Agreement has also helped reduce prices, although more gradually. Since its implementation in 2017, the agreement has established tariff elimination schedules of up to 10 years for certain categories. By 2022, Ecuador had already eliminated tariffs on nearly 1,300 items of EU origin, including pharmaceuticals, equipment, and medical supplies (Agent Comex EC, 2022).

As a result, European medical inputs such as surgical instruments, laboratory materials, and medicines now enter with reduced or zero tariffs. While this has led to some price reduction, its impact is less noticeable than in the Chinese case, since EU products tend to have a higher base cost due to their quality and brand reputation. Thus, although both agreements have reduced import prices, the China FTA has had a more substantial impact due to China's status as a low-cost supplier.

5.2 Quality of medical supplies and standards

China offers a wide range of medical products, from low-cost supplies to cutting-edge medical equipment. For basic inputs such as hypodermic needles, Chinese products generally meet essential functional standards and may carry international certifications (ISO, CE, FDA), depending on the manufacturer. However, concerns about quality consistency persist. With trade liberalization, Ecuadorian authorities have emphasized the need to strengthen sanitary controls. ARCSA is responsible for verifying the quality and safety of all Chinese products entering the country duty-free (EdiciónMédica, 2024).

Thus, while Chinese imports provide price advantages, it is critical not to compromise patient safety. In practice, many reputable Chinese manufacturers often OEMs (original equipment manufacturers) for Western brands offer good-quality products. However, low-cost suppliers with substandard products may also enter the market. For hypodermic needles, factors such as steel quality, sterility, and precision vary by manufacturer, and ARCSA must ensure all imported products meet national safety and technical standards.

Medical products from the EU are widely recognized for their high quality and reliability. The Multipart Agreement does not relax any technical requirements, as European products already comply with strict regulations (e.g., CE certification), facilitating their approval in Ecuador. Thanks to this agreement, "high-quality products" have entered the country, particularly from countries like Germany, France, and Spain.

For critical supplies such as specialized needles, sutures, and diagnostic tools EU suppliers offer excellent performance, traceability, and warranties. Their presence has improved the availability of premiumquality medical products in the Ecuadorian market.

5.3 Access, availability, and market each

The FTA eliminated barriers to imports from China on more than 60% of items immediately, including medical supplies. This translates into expanded access to a large volume of general-purpose medical supplies. Products that may have previously been expensive or scarce now flow easily.

Ecuador is even better positioned to quickly access Chinese medical supplies in the face of unexpected surges in demand or emergencies. Hypodermic needles, being of low value and high volume, can now be imported in larger quantities without tariff surcharges, ensuring sufficient stock in health centers. In addition, the speed and scale of Chinese production means that new inputs, such as innovative medical devices, can be sourced almost at the same time as they enter the global market.

The Agreement with the European Union, for its part, has allowed the entry of products that previously had limited access due to cost or quotas. With the entry into force of the Pact, equipment, spare parts, medicines,

supplies and technology from the EU enter the Ecuadorian market without restrictions. This means that Ecuadorian hospitals can acquire diagnostic equipment, surgical instruments, prostheses, laboratory reagents and other health-related products from Europe with greater economic and administrative ease.

Access not only means a lower price, but also commercial fluidity; the Agreement harmonizes norms and procedures to a certain extent, facilitating imports. An important fact is the trade relationship with Germany, one of the main European suppliers before signing with the EU, Ecuador imported millions in German medicines, reagents and medical instruments; after the Agreement, these imports are simpler and free of tariffs, increasing the domestic availability of such inputs. The EU offers access to state-of-the-art medical technology and specialties that complement the Chinese offer: while China provides mainly consumables and standard equipment, Europe allows access to specialized equipment and innovative drugs.

5.4 Trade dependency and market balance

Ecuador's trade dependence on China already existed before the FTA; a very high proportion of medical supplies were imported from China. Between 2007-2011, China contributed nearly 59% of Ecuador's imports of hypodermic needles, positioning itself as the dominant supplier. In 2023, China continued to be the main supplier of medical instruments and devices, with USD 62.8 million, approximately 29% of total imports in the category of medical supplies (OEC, 2024).

With the elimination of tariffs through the FTA, it is predictable that China's market share will increase even more, given its competitive power in price. This generates a growing trade dependency, Ecuador could become vulnerable to eventual disruptions in the Chinese supply chain due to geopolitical conflicts, logistical problems, etc. It also means that local suppliers or those from other countries could be displaced. It should be noted that the FTA included exclusions to protect sensitive domestic industries, but domestic production of basic medical inputs is virtually non-existent, so there were no reservations in this sector. As a result, there is no domestic counterweight and dependence on imports, especially from China, deepens. This lowers costs, but concentrates the risk in a single origin.

The Multi-Party Agreement diversified the sources without creating an equivalent dependency in magnitude, Europe represents an important but minor fraction of the total imported medical supplies. In 2023, Germany the largest supplier to the EU constituted about USD 29.6 million in medical instruments this represents 14% of the total imported (OEC, 2024).

Adding other European countries, the EU collectively can account for between 15 and 20% of imports in this area. This level, while significant, does not replace China or the U.S. The advantage here is that Ecuador spreads its dependence among multiple partners; in addition to China and the U.S., the EU now provides a substantial part of its needs in equipment, medicines and inputs. Instead of relying on a single country, it relies on several developed countries with strong supply chains. The advantage of having an agreement with a regional bloc such as the EU is that products from 27 countries can be sourced, which allows Ecuador to link up with different suppliers within Europe. For example, if a German manufacturer had problems, it could turn to an Italian or Spanish supplier, also taking advantage of the EU's tariff preferences. Therefore, the agreement with the EU tends to reduce the vulnerability associated with relying on few origins, promoting a more balanced supply. China has a high-cost benefit, but with a high dependence; on the other hand, the EU has a moderate benefit with diversified and less risky dependence in the long term.

5.5 Supplier Diversification

With respect to China, there is a concern that Ecuador's availability of suppliers may become more limited as Chinese supply becomes cheaper. Diversification implies having multiple sources for the same good or service. In the case of hypodermic needles, before the Agreement, Chinese, U.S., Colombian and Mexican suppliers, among others, were already competing to consolidate their position in the global market. China had an advantage in price, but other suppliers held markets due to quality, geographic proximity or previous trade agreements, such as the Andean Community, which facilitated imports from Colombia. Now, with the tariff preference for China, many importers opt almost exclusively for that origin for low-cost inputs, reducing purchases from third countries. This may affect regional suppliers, such as Andean or Mexican manufacturers, which could lose market share if they cannot match Chinese prices without tariffs. An CEPAL report prior to the signing warned that total liberalization with China would significantly increase imports from that country, requiring strategies to manage the trade deficit (Lima & Piñero, 2023).

On the other hand, the Agreement with the European Union has acted in the opposite direction. Traditionally, Ecuador imported its medical equipment and supplies mainly from the United States, Asia

(China, Japan) and some neighboring countries. Since the Agreement came into force, European companies have been able to compete in the Ecuadorian market. This can be seen in the variety of European products that have gained presence since 2017, the year the agreement came into force, new EU products enter in categories of hospital supplies, pharmaceuticals, etc., which previously had little participation.

For example, a local distributor can now import surgical gloves from Germany, vital signs monitor from Finland or specialized needles from Italy, expanding the catalog available beyond previous options. This diversification reduces the risk of shortages; if one country fails, there are others, and these can improve the competitiveness of suppliers as they compete on quality and price. It should be stressed that the diversification achieved has a practical limit: many basic inputs will continue to come from wherever they are cheapest (usually China or India), and many high-end inputs will continue to come from the U.S. or Europe at the importer's convenience. Even so, having the EU as a preferential partner has enriched Ecuador's supply alternatives, something that the FTA with China alone would not have achieved since it focuses on a single country.

5.6 Innovation and technological development

The FTA with China does not include a chapter dealing with technology transfer or cooperation in health research and development. Its main innovative effect comes from the rapid introduction of new products to the market. China today is the world's leading manufacturer and in medical devices it is no exception, from basic medical equipment or supplies to cutting-edge surgical robots. With the FTA, any Chinese innovation in medical devices can reach Ecuador faster and at a lower cost.

In addition, cost reduction frees up resources in hospitals that could be used for other improvements or training. However, in terms of local innovation, the availability of cheap imports can have a negative side, as it discourages local entrepreneurs from producing medical supplies, since competing against Chinese prices is difficult. Ecuador, in fact, lacks a robust domestic industry in medical devices, most inputs are imported, so the FTA reinforces a model of acquiring innovation externally, rather than developing it internally. However, there is a possibility that Chinese companies may see Ecuador as a hub to assemble or distribute inputs to the region, which could bring investment in technology. For now, the main innovative contribution of the FTA is to facilitate access to Chinese medical technology, which is advancing rapidly in certain fields, such as telemedicine and portable devices.

With the EU, the Agreement, by involving countries with advanced medical-pharmaceutical industries, creates an ideal environment for collaboration and knowledge transfer. While the Trade Agreement itself focuses on tariffs and market access, cooperation initiatives have emerged around it, for example, technical assistance from the EU to implement sanitary regulations, homologation of standards, among others. This may encourage Ecuador to raise its technical standards, a requirement for innovation. On the other hand, the facilitated importation of European high-tech equipment (laboratory, imaging, therapy, etc.) allows local doctors and engineers to be exposed to the latest in innovation, serving as a stimulus for research or local adoption.

Some European companies could establish representations or alliances with Ecuadorian companies, transferring know-how in the maintenance of sophisticated medical equipment, clinical training, etc. A concrete effect of the Agreement is that it expanded the supply of products with higher added value in the Ecuadorian market, a sign of diversification towards more advanced goods. However, as with China, Ecuador continues to be a major importer of medical technology. None of the agreements have so far meant the creation of manufacturing or research centers for medical supplies in the country. Innovation" is reflected more in the modernization of the health sector (which has better inputs) than in domestic productive innovation. In the medium term, the partnership with the EU could facilitate development programs (for example, the EU often supports projects in Latin America in the areas of health and innovation), which would be a collateral gain of the trade agreement.

6. Conclusion

This study aimed to analyze the role of trade agreements in the importation of medical supplies through a comparative case study of the China–Ecuador Free Trade Agreement and the Multipart Trade Agreement with the European Union. The analysis demonstrates that both agreements have significantly influenced the import dynamics of medical inputs in Ecuador by facilitating market access, reducing costs, and improving the availability of essential supplies for the national health system.

The China–Ecuador FTA has generated immediate effects, particularly in price reduction and increased supplier options. Thanks to the elimination of tariffs on over 4,600 Chinese product subcategories, Ecuadorian importers have been able to access high-demand medical products such as hypodermic needles, syringes, and hospital supplies at more competitive prices, increasing affordability for healthcare centers.

On the other hand, the Multipart Agreement with the European Union has favored the entry of high-quality medical inputs, especially in specialized and advanced technology segments. Although European products tend to be more expensive, they offer higher safety standards, certifications, and product traceability, which translates into long-term reliability and lower regulatory risk.

Among the key findings is that price continues to be the most decisive factor for imports to Ecuador, given the country's economic and healthcare realities. However, quality, supplier diversification, and innovation are crucial for strengthening the health system and reducing dependency risks. The study also highlights the importance of strengthening ARCSA's institutional capacity to ensure imported products meet safety and quality standards.

It is also evident that both agreements have different strengths: the China FTA is ideal for cost efficiency and supply volume, while the EU Agreement contributes to the introduction of sophisticated technology and international best practices. Ecuador should maintain a balanced trade strategy that leverages both partnerships while promoting local production of medical devices.

Lastly, it is recommended that public policies support technological transfer, encourage local production, and improve distribution logistics especially in rural areas so that the benefits of these trade agreements reach the entire Ecuadorian population. In doing so, Ecuador will not only ensure a sustainable and resilient healthcare supply chain, but will also make the most of the opportunities provided by its international trade policy.

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