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United States supply chains resiliency: the key role Latin America and the Caribbean could play

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Introduction

The disruption to the global supply chains in the context of COVID-19 made evident the shortcomings of having global supply chains spread out across the globe and re-opened the discussion about the advantages of having shorter, regionalized supply chains. Technology, automation, and additive manufacturing have been slowly reducing labor requirements for several tasks and therefore diminishing the need to produce in low labor costs countries-regions to supply markets far away. Climate change has also been encouraging consolidating production close to consumer markets to minimize the disruption risks of more frequent and severe weather events and to reduce their carbon footprint. The United States-China trade war made sourcing from China more expensive and threatened the disruption of supply chains geographically concentrated in China. Developing capabilities across regions, reduces the risks owing to global drawn-out supply chains that can be disrupted by events happening in other regions.

The Covid-19 pandemic revealed the vulnerability of supply chains to disruptions in countries that play a central role in global supply chains as is the case of some Chinese companies in electronics, auto industries, pharmaceuticals, metals, and personal protective equipment, among others. When the Chinese economy shutdown due to the outbreak of the new coronavirus disease, and restrictions were imposed on transport and travel, supply chains were disrupted around the globe, and U.S. manufacturers and distributors struggled to supply the U.S. market including of key COVID-19 medical equipment and supplies. This prompted policymakers and businesses to consider actions to improve the resiliency of supply chains to future shocks. Considerations include whether and how to incentivize additional production of health supplies and pharmaceuticals in the United States (reshoring) or in its neighboring countries (near-shoring), diversification of production and suppliers and addressing dependency in other industries such as pharmaceuticals, telecommunications, microelectronics, and or semiconductors, among others.

While diversification of production and suppliers is desirable, it can prove very costly if not an unsurmountable challenge. The cost of adding resiliency may not be feasible. Besides, often, the sophistication of the components involves manufacturing processes that require specialists. For example, companies like Apple and Qualcomm are entirely dependent on one company for their most advanced chips –Taiwan Semiconductor Manufacturing Company (TSMC), that represents the largest global market share of most advanced chipmaking processes (Shih, 2020). According to some experts, the magnitude of the challenge of finding or developing an alternate source of supply to TSMC is one of the reasons behind the Chinese government's Made in China 2025 initiative, the state-led industrial policy aimed at rapidly expanding its high-tech sectors and developing its advanced manufacturing base. There are, however, some industries that could diversify their supply base if they are willing to buy from higher-cost producers. Those are industries whose supply concentration was the result of prioritizing price and efficiency over diversity or resiliency.

This paper focuses on the impact on three industries to exemplify the disruption that took place in supply chains during the global pandemic; and the measures taken by the United States government to confront the disruption in the short run and protect the health and livelihood of its citizenry.

The United States auto industry and manufacturers in other large automobile manufacturer countries such as South Korea, Japan and Germany faced bottlenecks in their production lines because of the lack of availability of auto parts supplies from China.

The food industry suffered a significant blow. Farmers found it difficult to redirect their produce where the buyers were once their regular distribution channels were shut down and schools, restaurants and hotels cancelled orders. The result was large amounts of produce wasted in the fields, numerous farmers, and ranchers at the brink of bankruptcy and shortage of food in supermarkets and food banks.

China is a major global supplier of personal protective equipment (PPE), medical devices, antibiotics, and active pharmaceutical ingredients (API¹). Restrictions on its exports together with the spike in global demand as the COVID-19 pandemic spread worldwide resulted in shortages of critical medical supplies worldwide and in the United States, in particular. Consequently, several measures were taken to alleviate the shortage in the short run and a whole evaluation of supply chains was commissioned to the United States International Trade Commission to strengthen the resiliency of supply chains for future similar shocks.

The devastation caused by the outbreak of the global COVID-19 pandemic pushed governments to rethink several policies through the prism of the pandemic. However, concerns over the reliance on one country or small group of countries for the supply of critical goods for the protection of the livelihood, health and safety of the citizens preceded the pandemic. Central to those concerns was the question of whether countries should be less dependent on a dominant pharmaceutical supplier by increasing domestic manufacturing and the diversification of the sources of medicines as a precondition for ensuring the safety and reliability of the drug supply chain and at what cost.

The need to have a realignment of the drug supply chain was already an issue well before the eruption of Covid-19 due in part to the increased dependency on China as the critical supplier of APIs and even some finished pharmaceutical products. The United States-China trade war intensified this concern considerably in the past few years. The threat that, in the context of escalating tensions, China could impose export restrictions of APIs or finished pharmaceuticals posed serious national security concerns. Covid-19 amplified these concerns, in part, because the pandemic started in China where the lockdown prevented companies from continuing with their manufacturing schedule, forcing a re-evaluation of the vulnerabilities of the drug supply chain, not just in the United States but also in the European Union and in many other countries throughout the world. In the first few months of 2020 there were over twenty bills introduced in the U.S. Congress to increase domestic production and address the vulnerabilities of the supply chain.

Arguably, policy decisions regarding a problem that was long in the making and that is the result of factors other than the once-in-a-lifetime-shock like the outbreak of the new coronavirus disease requires thoughtful consideration of the factors that led to the geographic concentration of critical pharmaceuticals and APIs and the dependence of most of the world on the production of one or a few countries as well as the consequences of decoupling, being through domestic production or diversification of sources when possible. This is the case of the United States dependency on China's production of APIs and other pharmaceutical products.

¹ APIs are the part of a pharmaceutical product that contains the active drug.

This document looks at the disruption in supply chains that were more prevalent in the United States during the 2020 Covid-19 pandemic as well as the measures taken by the United States government to mitigate the effects in the short run. Then looks at the United States trade in pharmaceuticals and APIs to document the international sources of United States consumption in those industries as well as the progressive concentration of API sourcing in China, the reasons behind it, the potential solutions, and the opportunities they may present to the Latin America and the Caribbean region.

Covid-19 pandemic disruptions and the United States response

This section highlights the disruptions experienced by the automotive supply chain, the food supply chain and the medical supply and pharmaceuticals to exemplify the magnitude and effects of the COVID-19 pandemic and the scope of challenges that the countries and the private sector need to address looking forward to prevent them in future crisis.

The North American automotive supply chain

The global and North American automotive supply chain was severely affected by the pandemic. China is a major supplier of parts to auto plants around the world – shipping nearly US\$35 billion of parts in 2018 (COMTRADE data). About US\$20 billion of Chinese made parts were exported to the United States that year, according to the U.S. International Trade Administration. While some of those parts go to auto parts retail stores, a large percentage of them go to assembly lines and are used to build cars, therefore affecting the North American supply chain.

Mexico's auto distributors association AMDA expected sales of all new vehicles made in the country to drop by at least 25.5% in 2020 to reach some 982,000 vehicles – or more than 330,000 units less than the previous year – which would also be similar to figures during the 2009 financial crisis. The Mexican Automotive Industry Association AMIA estimates that the automotive industry makes up about 4% of the country's gross domestic product and generates nearly 1 million direct jobs.

Since NAFTA, the United States-Mexico-Canada Agreement (USMCA) precursor, entered into force 26 years ago, automobile production has been strongly linked among the three countries party to the agreement (Canada, Mexico and the United States) through supply chains. When COVID-19 struck, measures taken at different points in time by the governments of the three countries to contain the spread of the pandemic and protect the health of workers halted production in several activities, including operations in the auto sector. The closely interconnected supply chains were disrupted, highlighting the need to coordinate health emergency measures among the three governments.

The automobile sector was given extra time to adjust to the new rules of origin for the sector embedded in the USMCA, which entered into force 1 July. The auto sector needs more time in part because the COVID-19 has caused temporary closure of some production facilities while others have switched operations from the production of cars to the production of medical equipment.

Regional content rules in the USMCA will require 75% North American content for light vehicles compared to 62.5% under NAFTA and 40% content for such cars from areas that reach a certain wage threshold (“high wage” areas). This is to be phased in over three to four years, but automakers must certify compliance with the initial requirements when the agreement takes effect.

Table 1 includes information on several actions taken by the top car makers in the United States On 8 April 2020, the United States Department of Health and Human Services issued the first contract to General Motors of US\$489 million to build 30,000 ventilators under the Defense Protection Act.

Table 1
Selected Actions by Auto Industry

	Status	Date of Closure	Date of Re-opening	Re-opened to Other Manufacturing	Furloughed Employees	Number of Employees*
General Motors	Open	19-Mar	18-May	Ventilators and PPE**	50,000	86,400
Ford Motor Company	Open	19-Mar	18-May	Ventilators and PPE	50,000	85,000
Toyota Motor Corporation	Open	23-Mar	11-May		5,000	136,000
Fiat-Chrysler (FCA)	Open	18-Mar	18-May	Face Mask Production	50,000	77,000
Honda Motor Company	Open	18-Mar	11-May		14,000	27,000
Nissan Motor Company	Closed	20-Mar	Indefinite		10,000	22,000
Hyundai-Kia Auto Group	Open	30-Mar	5-May			31,000
Subaru Corporation	Open	29-Mar	18-May			5,300
Volkswagen Group	Open	17-Mar	18-May			8,000
Mazda	Open	24-Mar	1-Jun			20,000
Tesla	Open	23-Mar	18-May	Face Mask Production		48,000
BMW Group	Open	29-Mar	4-May		11,000	11,000
Volvo	Open	26-Mar	11-May			17,000

Source: ECLAC on the basis of a collection of newspaper articles, industry specific publications and periodic trade publications.

The food supply chain

Food supply chains were also severely affected by the pandemic. As restaurants, hotels and schools closed, U.S. farmers found it difficult to redirect their produce where the buyers were and even when they did, conditions were not adequate to absorb most of it. Retailers saw a spike in demand for food products as most meals were now being prepared at home, but that was not enough to absorb the perishable products that were meant for schools and other businesses. Even food banks and Meals on Wheels programs, which were overwhelmed with demand, did not have the number of refrigerators or volunteers to absorb the surplus, at the beginning of the pandemic. At some point, Dairy Farmers of America, the largest dairy cooperative in the United States, estimated that farmers were dumping as many as 3.7 million gallons of milk each day.

Moreover, many meat processing plants were forced to temporarily close after several workers tested positive for COVID-19. This contributed to an increased pressure in the supply of food to the domestic market, in particular, meat supply. The food processing industry is very vulnerable to the new coronavirus outbreak as employees work near one another. Compounding this issue was the lack of enough testing that left untested potentially infected workers, precipitating the infection's spread.

The list of major meat processors that have had to shut down plants includes Smithfield Foods that processes about 5% of the U.S.' pork production, JBS USA, the world's largest meat processor, Cargill's facility in Pennsylvania where it produces steaks, ground beef and ground pork, and Tyson's pork plant in Iowa.

In this context, the Department of Agriculture (USDA) announced the Coronavirus Food Assistance Program (CFAP). The program includes two major elements:

- (i) Direct Support to Farmers and Ranchers: The program will provide US\$ 16 billion in direct support based on actual losses for agricultural producers where prices and market supply chains have been impacted and will assist producers with additional adjustment and marketing costs resulting from lost demand and short-term oversupply for the 2020 marketing year caused by COVID-19.
- (ii) USDA Purchase and Distribution: USDA will partner with regional and local distributors, whose workforce has been significantly impacted by the closure of many restaurants, hotels, and other food service entities, to purchase US\$ 3 billion in fresh produce, dairy, and meat. The distributors and wholesalers will then provide a pre-approved box of fresh produce, dairy, and meat products to food banks, community and faith-based organizations, and other non-profits serving Americans in need.

On top of these targeted programs USDA announced it would utilize other available funding sources to purchase and distribute food to those in need.

Fisheries assistance

On 7 May, 2020, the U.S. Department of Commerce announced the allocation of US\$300 million in fisheries assistance funding provided by Sec. 12005 of the CARES Act, to states, Tribes, and territories with coastal and marine fishery participants who have been negatively affected by COVID-19. U.S. fisheries support 1.7 million jobs and generate US\$200 billion in annual sales.

Fishery participants eligible for funding include Tribes, commercial fishing businesses, charter/for-hire fishing businesses, qualified aquaculture operations, processors, and other fishery-related businesses. To figure out eligibility and apply for these funds, they should work with their state marine fisheries management agencies, territories, or Tribe. The following table shows how these funds were allocated.

Table 2
Summary of Allocations*
(in dollars)

Entity	Allocation	Entity	Allocation	Entity	Allocation	Entity	Allocation
Alaska	50,000,000	New Jersey	11,337,797	Pennsylvania	3,368,086	South Carolina	1,525,636
Washington	50,000,000	Texas	\$9,237,949	Alabama	3,299,821	Delaware	1,000,000
Massachusetts	28,004,176	New York	6,750,276	Rhode Island	3,294,234	Puerto Rico	1,000,000
Florida	23,636,600	North Carolina	5,460,385	New Hampshire	2,732,492	United States Virgin Islands	1,000,000
Maine	20,308,513	Federally Recognized Tribes on the West Coast	5,097,501	American Samoa	2,553,194	Federally Recognized Tribes in Alaska	1,000,000
California	18,350,586	Virginia	4,520,475	Georgia	1,921,832	Guam	1,000,000
Oregon	15,982,827	Hawaii	4,337,445	Connecticut	1,835,424	Commonwealth of the Northern Mariana Islands	1,000,000
Louisiana	14,785,244	Maryland	4,125,118	Mississippi	1,534,388	Total	300,000,000

Note: * Final award amounts will be different due to Hollings and other assessments.

Source: ECLAC on the basis of NOAA (<https://www.fisheries.noaa.gov/feature-story/commerce-secretary-announces-allocation-300-million-cares-act-funding>)

In addition, the Administration introduced in May 2020 an Executive Order to increase the United States' competitiveness in the seafood industry and protect its seafood supply chain. This order instructs agencies to expand sustainable seafood production in the United States, including furthering more efficient and predictable aquaculture permitting processes, accelerating regulatory reform to maximize commercial fishing, and upholding common-sense restrictions on seafood imports that do not meet U.S.

standards. President Trump also announced the availability of US\$ 300 million to support fishermen and related businesses hurt by the coronavirus.

The medical supplies and equipment value chain

The health crisis that started in China at the beginning of 2020, reduced exports from the Asian country and, among other effects, led to shortages of critical medical supplies worldwide and in the United States, in particular. China is a major global supplier of personal protective equipment (PPE), medical devices, antibiotics, and active pharmaceutical ingredients (API) (Sutter, 2020).

Shortages have been deepened by the spike in the global demand of these products as the COVID-19 pandemic spread worldwide, and restrictions were placed on exports of critical products in the fight against the novel coronavirus by several countries. Analysts and industry groups have also pointed to the role of tariffs in diminishing U.S. imports of health and medical products from China, contributing to the shortage of medical equipment. Tariffs on these products had been raised starting in September 2019 in the context of U.S.-China trade tensions.

The U.S. trade response to the COVID-19 crisis has revolved around reducing its dependence on foreign production of medical supplies through diversification of supply chains and of taking measures to promote domestic production of critical medical supplies and equipment. The U.S. also joined a host of other countries in restricting exports of medical supplies starting 10 April 2020.

- On 17 March, the United States Trade Representative (USTR) approved the exclusion of surgical masks and disposable respirators from the list of products imported from China subject to ad valorem duties in the context of the U.S.-China trade dispute. U.S. tariffs had been penalizing U.S. imports of surgical masks and disposable respirators from one of the world's largest suppliers.
- President Trump formally invoked the Defense Production Act (DPA) to fill the gaps between medical supplies to fight the COVID-19 pandemic. On 2 April, the U.S. Administration invoked the DPA to require 3M to prioritize orders from the Federal Emergency Management Agency (FEMA) for N95 respirators. Concurrently, President Trump requested that 3M increase the number of respirators imported from its overseas operations, China among others, into the United States. The Administration also requested that 3M cease exporting respirators currently manufactured in the United States to Canada and Latin American countries – in 2019, 34% of the 3M U.S. production of N95 was exported to Canada and 30% to Mexico. This last request was later dropped. Several of the largest car companies including General Motors, Ford, Fiat-Chrysler, Tesla have also switched operations from car production to masks, ventilators, and face shields production. At the end of July, KODAK received a US\$765 million United States International Development Finance Corporation (DFC) loan under the Defense Production Act, to help expedite domestic production of drugs that can treat a variety of medical conditions and release the U.S. reliance on foreign sources.
- On 7 April, FEMA issued a temporary final rule published in the Federal Register Notice of 10 April 2020 (see new 44 CFR 328.102(a)), "Prioritization and Allocation of Certain Scarce or threatened Health and Medical Resources for Domestic Use". The temporary final rule established that some medical equipment needed to combat COVID-19

cannot be exported from the U.S. without “explicit approval” from FEMA. This rule would be effective from 10 April 2020 to 10 August 2020 and applied only to “designated materials” including filtering facepiece respirators (e.g. those designated as N95, N99, N100, R95, R99, R100, or P95, P99, P100); elastomeric, air-purifying respirators and appropriate particulate filters/cartridges; PPE surgical masks; and PPE gloves or surgical gloves. This new U.S. export restriction means FEMA could limit what companies like 3M can sell to hospitals in Canada and Mexico.

- On 14 April, the U.S. Export-Import Bank announced new temporary restrictions – through 30 September 2020 – on financing U.S. exports of scarce medical supplies, including respirators, masks, gloves, Tyvek suits, face shields and similar protective wear needed to fight the COVID-19 pandemic. According to authorities of the U.S. EX-IM bank, financing for medical equipment exports is a small part of the overall financing portfolio – less than 1%.
- The Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136), includes several provisions that seek to enhance the understanding of U.S. medical supply chain dependencies (Sutter, 2020), including:
 - expand drug shortage reporting requirements.
 - require certain drug manufacturers to draw up risk management plans.
 - require the U.S. Food and Drug Administration (FDA) to maintain a public list of medical devices that are determined to be in shortage; and
 - direct the National Academies of Science, Engineering, and Medicine to conduct a study of pharmaceutical supply chain security.

COVID-19 related medical supplies, equipment, and pharmaceutical products

On April 6, the Senate Finance Committee and the House of Representatives Ways and Means Committee asked the U.S. International Trade Commission (USITC) to identify the goods that are relevant to responding to the COVID-19 crisis.

The report identified 112 product lines at the harmonized tariff schedule 10-digit (HTS-10) reporting numbers classified in 7 categories : COVID-19 test kits/testing instruments; disinfectants and sterilization products; medical imaging, diagnostic, oxygen therapy, pulse oximeters, and other equipment; medicines (pharmaceuticals); non-PPE medical consumables and hospital supplies; personal protective equipment; and other.

This section follows the USITC’s classification of COVID-19 related products to describe U.S. international trade in medical supplies, equipment as well as pharmaceutical products².

² Trade in medical supplies, equipment and medicines is much broader than what is considered in this section.

The U.S. runs a trade deficit in COVID-19 related products³. In 2019, the trade deficit amounted to almost US\$60 billion as compared to US\$8 billion 15 years ago.

Table 3
U.S. Covid-19 related trade
(in billions of dollars)

	2005	2010	2015	2019
Imports	20.72	30.93	45.72	105.32
Exports	12.57	22.02	23.36	46.39
Trade Balance	-8.15	-8.91	-22.36	-58.93

Source: ECLAC using USITC Dataweb.

China is the second top U.S. supplier of COVID-19 related products, after Ireland. Mexico and Canada are the fourth and fifth, respectively.

Table 4
Top 10 country sources of Covid-19 related products
(in billion dollars)

	2005	2010	2015	2019
Ireland	2.11	1.07	4.82	14.17
China	2.99	5.61	8.19	12.32
Germany	1.50	1.72	2.28	12.23
Mexico	2.90	4.56	5.81	8.79
Canada	1.38	2.18	2.42	6.04
Belgium	0.40	0.83	1.18	5.95
Switzerland	0.28	0.47	0.78	5.08
Singapore	0.30	0.36	0.96	4.18
Japan	1.39	1.69	2.11	4.15
United Kingdom	1.28	1.51	1.38	3.42

Source: ECLAC using USITC Dataweb

OECD countries are the main suppliers of COVID-19 related pharmaceutical products to the U.S.. India and Singapore are the only non-OECD countries among the top 10 suppliers (Table 5).

The U.S. depends on global and hemispheric supply chains. In many cases, the production facilities of high quality, safe PPE are in nearby Central America, the Caribbean, and Mexico. As the U.S looks to health care through a national security lens and reevaluates the benefits and costs of diversifying sources of supply, new opportunities could open for countries in Latin America and the Caribbean to export to the U.S. market. For the U.S. this would have the benefit of diversifying the supply chain with lower production costs within the hemisphere (near-shoring).

³Chad P. Bown of the Peterson Institute of International Economics has identified a set of HTS6 codes that best reflect the medical supply and equipment products that are in short demand because of the COVID-19 pandemic. Although there is some overlap with those identified in the USITC report, they are not identical. Sutter, 2020 also identified HS-6 medical supplies, equipment, and pharmaceutical products.

Table 5
Top 10 country sources of medicines (pharmaceutical) COVID-19 related
(in billion dollars)

	2005	2010	2015	2019
Ireland	0.03	0.02	3.21	6.4
Belgium	0.35	0.77	1.09	5.12
Switzerland	0	0.01	0.04	2.67
Germany	0.08	0.14	0.17	2.6
Canada	0.31	0.72	0.6	2.44
India	0.16	0.32	0.6	2.11
Singapore	0	0	0	1.96
South Korea	0	0	0	1.33
Denmark	0	0	0.01	1.14
United Kingdom	0.43	0.6	0.36	1.07

Source: ECLAC using USITC dataweb

Within Latin America and the Caribbean, Mexico, Costa Rica, Brazil, and the Dominican Republic are the main sources of COVID-19 products to the United States. These four countries represent 98% of the region's exports to the United States.

Table 6
U.S. imports from LAC countries of COVID-19 related products
(in million dollars)

	2005	2010	2015	2019
Mexico	2898.4	4558.6	5806.7	8793.6
Costa Rica	436.1	576.8	1168.4	1692.7
Dominican Rep	498.6	649.2	867.9	1008.6
Brazil	88.5	353.7	511.0	422.2
Honduras	65.6	68.4	97.7	96.2
Uruguay	0.6	0.8	28.9	43.3
Guatemala	12.4	7.4	20.1	28.4
Colombia	11.0	19.0	37.4	25.9
Nicaragua	0.8	1.2	3.7	13.5
El Salvador	1.0	1.8	3.6	7.6
Argentina	3.0	5.2	3.4	6.5
Panama	0.5	0.1	0.2	6.1
Chile	3.5	2.3	2.8	6.0
Ecuador	0.4	2.9	1.0	3.8
Peru	1.2	0.9	4.3	2.8
Haiti	1.5	0.3	0.8	1.3
Paraguay	0.1	0.1	0.6	0.5
Venezuela	3.8	0.4	0.1	0.4
Jamaica	0.2	4.3	0.4	0.2
Trin & Tobago	1.1	0.1	0.1	0.2
St Lucia	3.7	2.3	0.0	0.2
Bahamas	0.0	0.0	0.1	0.1
Bolivia	0.0	0.1	0.1	0.1
Dominica	0.8	0.2	0.0	0.1
Grenada	0.1	0.0	0.0	0.0
St Vinc & Gren	0.0	0.0	0.0	0.0
Antigua Barbuda	0.0	0.0	0.0	0.0
Barbados	0.1	0.2	0.0	0.0
Guyana	0.0	0.0	0.0	0.0
St Kitts-Nevis	0.0	0.0	0.0	0.0
Suriname	0.0	0.0	0.0	0.0
Belize	0.0	0.0	0.0	0.0
Total	4032.7	6256.0	8559.4	12160.3

Source: ECLAC on the basis of USITC dataweb

Table 7 presents United States imports of COVID-19 related medicines from Latin American and the Caribbean. Mexico and Brazil are the main suppliers of COVID-19 medicines to the United States. There was a significant increase in imports from the region of these kind of medicines, especially from Mexico and Costa Rica.

Table 7
U.S. imports of COVID-19 related medicines from LAC countries
(in million dollars)

	2005	2010	2015	2019
Mexico	0.52	0.38	0.43	91.16
Brazil	0	22.7	49.06	47.59
Colombia	0	0	0	3.05
Argentina	0	0	0	0.58
Costa Rica	0	0	0.17	0.57
Guatemala	0	0	0	0.16
Honduras	0	0	0	0.06
Dominican Republic	0.98	0	0	0
Total	1.50	23.08	49.67	143.19

Source: ECLAC on the basis of USITC dataweb

More broadly, Mexico, Brazil and the Dominican Republic are the main Latin America and the Caribbean suppliers of pharmaceutical and antibiotics to the United States. These include pharmaceuticals and antibiotics that may or may not be related to Covid-19. There was also a significant increase in the value of United States imports from the region of pharmaceutical and antibiotics—Costa Rica, Dominican Republic, and Colombia are the countries that show the largest increase in percentual terms.

Table 8
US imports of pharmaceutical and antibiotics from LAC, by countries
(in million dollars)

Country	2005	2010	2015	2019
Mexico	312	253	300	502
Brazil	65	156	188	181
Dominican Rep	3	7	10	44
El Salvador	0	0	0	11
Colombia	3	3	3	10
Argentina	0	4	5	6
Costa Rica	0	10	0	3
Total U.S. imports from Latin America and the Caribbean	390	436	523	759

Source: ECLAC usingf USITC dataweb

Table 9 provides the list of pharmaceutical and antibiotic products exported by Mexico, Brazil and the Dominican Republic to the United States. Highlighted in grey are exports of APIs or similar.

Table 9
US imports of pharmaceutical products and antibiotics from Mexico, Brazil, Dominican Republic, by product
(in dollars)

HTS Code	Product description	2010	2015	2020	
3004.90	MEDICAMENTS, IN MEASURED DOSES, ETC. (EXCLUDING VACCINES, ETC., COATED BANDAGES ETC., AND PHARMACEUTICAL GOODS), NESOI	199073714	199326888	330445095	
3005.10	ADHESIVE DRESSINGS AND OTHER ARTICLES HAVING AN ADHESIVE LAYER	13221735	29386373	86931788	
3005.90	WADDING, GAUZE, BANDAGES AND SIMILAR ARTICLES, IMPREGNATED OR COATED WITH PHARMACEUTICAL SUBSTANCES FOR MEDICAL, SURGICAL ETC. PURPOSES, NESOI	10609827	34515803	42981327	
3006.70	GEL PREPARATIONS FOR USE IN HUMAN AND VETERINARY MEDICINE AS LUBRICANT FOR OPERATIONS OR PHYSICAL EXAMS OR AS A COUPLING AGENT B/W BODY AND MEDICAL IN	6844311	14474403	18848300	
3006.50	FIRST-AID BOXES AND KITS	6115982	5714576	8607184	
Mexico	2941.10	PENCILLINS AND DERIVATIVES WITH A PENICILLANIC ACID STRUCTURE; SALTS THEREOF	7941962	3670700	7444787
	2941.90	ANTIBIOTICS, NESOI	8821045	11840077	5675669
	3001.90	HEPARIN AND ITS SALTS; OTHER HUMAN OR ANIMAL SUBSTANCES PREPARED FOR THERAPEUTIC OR PROPHYLACTIC USES, NESOI	84263	60900	855293
	3004.20	MEDICAMENTS, IN MEASURED DOSES, ETC., CONTAINING ANTIBIOTICS, NESOI	382539	417580	633132
	3003.90	MEDICAMENTS (EXCLUDING VACCINES, BANDAGES AND PHARMACEUTICAL GOODS) NESOI, OF TWO OR MORE MIXED CONSTITUENTS, NOT IN MEASURED DOSES, ETC.	74047	172753	6875
	3002.20	VACCINES FOR HUMAN MEDICINE	0	0	3600
	3004.49	MEDICAMENTS CONTAINING ALKALOIDS OR DERIVATIVES THEREOF, NESOI, PUT UP IN MEASURED DOSES OR IN FORMS OR PACKINGS FOR RETAIL SALE	0	0	2726
	3004.10	MEDICAMENTS, IN MEASURED DOSES, ETC., CONTAINING PENICILLINS OR DERIVATIVES THEREOF, OR STREPTOMYCINS OR THEIR DERIVATIVES	0	15233	0
			253171435	299597301	502437796
	3004.20	MEDICAMENTS, IN MEASURED DOSES, ETC., CONTAINING ANTIBIOTICS, NESOI	23482600	50327288	65535597
3005.10	ADHESIVE DRESSINGS AND OTHER ARTICLES HAVING AN ADHESIVE LAYER	74040916	82855153	56509084	
3004.90	MEDICAMENTS, IN MEASURED DOSES, ETC. (EXCLUDING VACCINES, ETC., COATED BANDAGES ETC., AND PHARMACEUTICAL GOODS), NESOI	38576969	43976135	47809975	
2941.90	ANTIBIOTICS, NESOI	17027698	6619396	6185288	
3005.90	WADDING, GAUZE, BANDAGES AND SIMILAR ARTICLES, IMPREGNATED OR COATED WITH PHARMACEUTICAL SUBSTANCES FOR MEDICAL, SURGICAL ETC. PURPOSES, NESOI	52464	2466612	4506862	
3001.90	HEPARIN AND ITS SALTS; OTHER HUMAN OR ANIMAL SUBSTANCES PREPARED FOR THERAPEUTIC OR PROPHYLACTIC USES, NESOI	1927910	1368968	873620	
Brazil	3004.49	MEDICAMENTS CONTAINING ALKALOIDS OR DERIVATIVES THEREOF, NESOI, PUT UP IN MEASURED DOSES OR IN FORMS OR PACKINGS FOR RETAIL SALE	0	0	6868
	3003.20	MEDICAMENTS CONTAINING ANTIBIOTICS, NESOI, NOT PUT UP IN MEASURED DOSES OR RETAIL PACKINGS	0	0	4426
	3002.20	VACCINES FOR HUMAN MEDICINE	1100040	0	2309
	2941.20	STREPTOMYCINS AND THEIR DERIVATIVES; SALTS THEREOF	0	0	0
	2941.30	TETRACYCLINES AND THEIR DERIVATIVES; SALTS THEREOF	0	0	0
	3003.90	MEDICAMENTS (EXCLUDING VACCINES, BANDAGES AND PHARMACEUTICAL GOODS) NESOI, OF TWO OR MORE MIXED CONSTITUENTS, NOT IN MEASURED DOSES, ETC.	4328	0	0
	3006.50	FIRST-AID BOXES AND KITS	0	0	0
		156212925	187613552	181434029	

Table 9 (Cont.)

HTS Code	Product description	2010	2015	2019	
3005.10	ADHESIVE DRESSINGS AND OTHER ARTICLES HAVING AN ADHESIVE LAYER	830035	324000	34849417	
Dom. Republic	3005.90	WADDING, GAUZE, BANDAGES AND SIMILAR ARTICLES, IMPREGNATED OR COATED WITH PHARMACEUTICAL SUBSTANCES FOR MEDICAL, SURGICAL ETC. PURPOSES, NESOI	6186503	9231424	9222990
	3004.90	MEDICAMENTS, IN MEASURED DOSES, ETC. (EXCLUDING VACCINES, ETC., COATED BANDAGES ETC., AND PHARMACEUTICAL GOODS), NESOI	207736	188592	165400
	3006.70	GEL PREPARATIONS FOR USE IN HUMAN AND VETERINARY MEDICINE AS LUBRICANT FOR OPERATIONS OR PHYSICAL EXAMS OR AS A COUPLING AGENT B/W BODY AND MEDICAL IN	0	0	66903
	3004.20	MEDICAMENTS, IN MEASURED DOSES, ETC., CONTAINING ANTIBIOTICS, NESOI	0	0	0
			7224274	9744016	44304710

Source: Authors using USITC dataweb

Beyond Covid-19: United States imports of pharmaceutical products and antibiotics

The United States has a large, geographically diverse pharmaceutical industry that is well inserted in global supply chains. The industry is comprised of large multinational firms as well as small and medium enterprises (SMEs). According to the USITC (2020), in 2017, 75% percent of the pharmaceutical 5000 establishments were SMEs with just 10% of the value of sales while 25% of the establishments were large and sold 90% of the industrial sales value. The distribution network of pharmaceutical supplies is concentrated in only three companies that distribute between 90-95% of the pharmaceuticals consumed in the United States. Production facilities take an average of five years to start up.

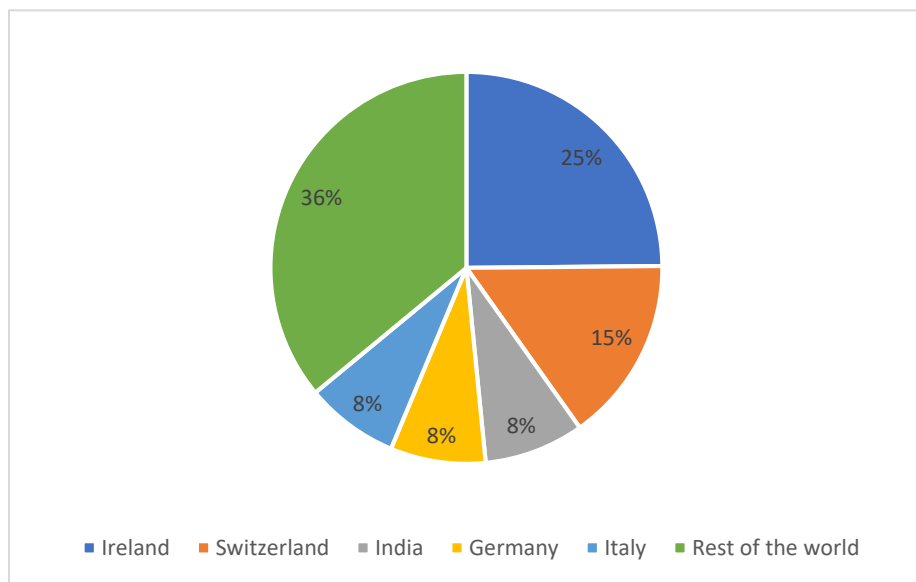
The United States is a significant producer of pharmaceutical products with a value of US\$268.7 billion sold in 2019. The bulk of the shipments (73%) were pharmaceutical preparations (in vivo diagnostic substances and non-biological pharmaceutical preparations), followed by biologics with 15%. In vitro diagnostic substances and APIs captured each 6% of the shipments. During the first nine-month of 2020, domestic shipments of pharmaceuticals reached US\$221 billion, 11% more than in the same period the year prior. Over the last 6 years, prices of pharmaceutical preparations have increased about 30%, those of biologics 15% while APIs have remained stable in price (USITC, 2020)

United States imports of finished pharmaceutical products reached US\$87.6 billion in 2019 (Table 10) and came mainly from developed countries such as Ireland, Switzerland, Germany, and Italy. In 2019, 25% of U.S. imports of those products came from Ireland, 15% from Switzerland and Germany, Italy and India supplied 8% of the US market each (figure 1). Together these five countries represented 64% of U.S. imports of those products. China, India, and Mexico are the only developing countries among the top 20 suppliers of pharmaceutical and antibiotics to the United States (Table 10). India is the third top supplier after Ireland and Switzerland, China is the twelfth and Mexico the seventieth.

However, China, India, Canada, and Mexico are the principal suppliers by volume (USITC, 2020). China and India specialize in low unit-value products, largely generic pharmaceuticals and commodity chemicals used in a variety of pharmaceuticals (including generics), which are significantly lower in value than the novel APIs and promulgations.

During the first nine months of 2020, United States pharmaceutical imports from China increased 46% by volume, compared to the same period 2019. United States imports from China, by volume, were APIs (69%) and, to a lesser extent, pharmaceutical preparations (27%).

Figure 1
United States imports of pharmaceuticals and antibiotics, 2019
(in percentages)



Notes: Products included in this table are the 6-digit -Harmonized Tariffs Schedule codes used in CRS and USITC reports, for a complete list of products included see Appendix.

Source: Authors using USITC dataweb.

United States reliance on China over the supply of key pharmaceutical products and medicines does not rest on the finished product but rather the inputs required for their production. Key among them are the Active Pharmaceutical Ingredients (API⁴). Although, data on United States imports of API is not readily available, other data is used as proxies to assess the dependency of the United States on foreign suppliers. Chapter 29 of the Harmonized Tariffs Schedule (HTS) includes all organic chemicals of which some are API. Table 11 shows that United States imports of organic chemicals increased significantly from US\$45 billion in 2009 to US\$54 billion in 2019. Imports from China have increased more than from the rest of the world growing China’s participation in the United States import market of organic chemicals from 9% to 15% over the same period.

⁴ In simple terms, APIs are the chemicals or biological molecules used in the composition and the production of any drug. More technical definitions in the United States and Europe follow.

According to the U.S. Code, an active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.⁴

Consistently, the European Union defines it as: “Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.”⁴

Table 10
United States imports of pharmaceutical products and antibiotics
(in billions of dollars)

Country	2005	2010	2015	2019
Ireland	5.9	8.7	13.9	21.8
Switzerland	0.9	4.2	8.2	13.4
India	0.3	2.3	5.7	7.2
Germany	2.7	3.8	5.7	6.9
Italy	1.4	1.0	2.7	6.8
Belgium	0.8	2.1	3.6	5.6
Canada	2.1	3.6	4.4	4.6
Singapore	1.4	1.8	1.2	3.2
United Kingdom	3.7	3.9	3.8	3.1
Japan	1.6	1.7	1.1	2.6
France	3.3	3.3	1.3	2.2
China	0.4	0.8	1.3	1.8
Israel	1.4	5.0	5.6	1.7
South Korea	0.0	0.0	0.1	1.4
Denmark	0.1	0.1	0.1	1.2
Spain	0.5	0.6	0.4	0.7
Mexico	0.3	0.3	0.3	0.5
Austria	0.2	0.4	0.4	0.5
Sweden	1.0	0.5	0.3	0.3
Netherlands	0.2	0.3	0.1	0.3
Total US imports	28.9	46.0	61.3	87.6

Notes: Products included in this table are the 6-digit -Harmonized Tariffs Schedule codes used in CRS and USITC reports, for a complete list of products included see Appendix. Table A.1

Source: Authors using USITC dataweb.

Narrowing down United States imports of Chapter 29 to the products at the HTS6 level that are closer to API such as antibiotics, vitamin C, ibuprofen, aspirin and acetaminophen⁵, Figure 2 shows that China is the main supplier with 36% of imports in 2019.

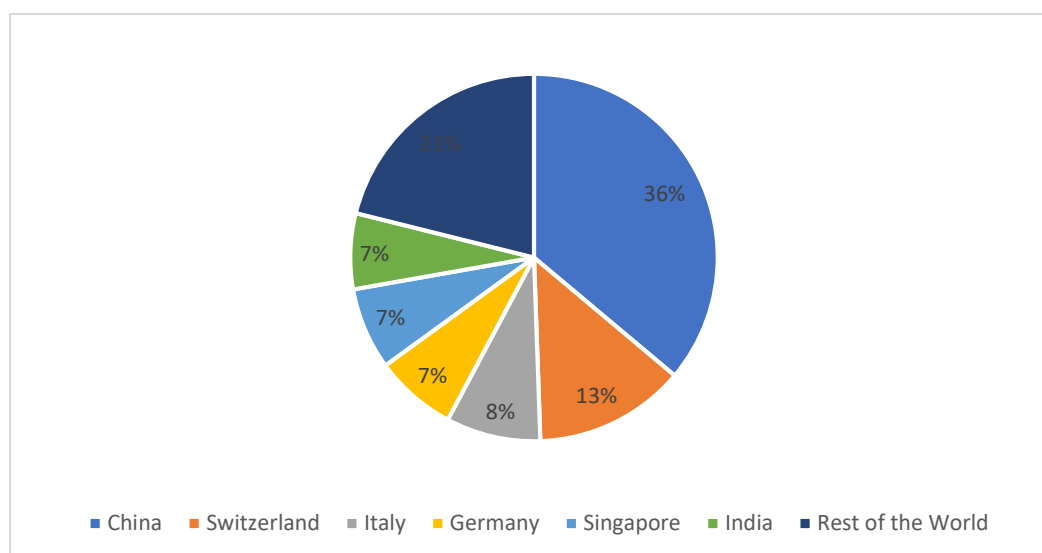
⁵ For a complete list of the codes included see Table A.2

Table 11
US imports of organic chemicals (HTS Chapter 29)
(in billion dollars)

	Total US imports in billion dollars			China		
	2009	2014	2019	2009	2014	2019
US Imports	45	54	54	4	7	8
Share				9%	13%	15%

Source: Authors using USITC Dataweb

Figure 2
US imports of antibiotics and other API ingredients



Source: Authors using USITC dataweb

With its accession to the World Trade Organization (WTO) in 2001, China focused its efforts on achieving economic growth, including through the expansion of the pharmaceutical industry. For the past twenty years, it mostly devoted its efforts to the production of basic chemicals and APIs and has become the lead supplier of APIs by volume in the global market (WHO, 2017). Given this success, now China seems to be extending such focus to the development and production of finished pharmaceutical products. This also seems to respond to the fact that profit margins for APIs are very low (WHO, 2017).

Table 12 shows the rapid increase in the last ten years in some particular markets: antibiotics and penicillin where China increased its share of the United States import markets from 1% to 52% in the case of penicillin and from 15% to 37% in antibiotics. Ibuprofen, aspirin, and acetaminophen also show a significant increase as shown in the following tables.

Table 12
United States imports of Antibiotics, Ibuprofen, Aspirin and Acetaminophen
(in million dollars)

	Total US imports			China		
	2009	2014	2019	2009	2014	2019
Antibiotics (HTS 2941)	908	697	841	132	188	307
Penicilin (HTS 294110)	146	123	114	1	23	59
Share antibiotics				15%	27%	37%
Share peniciline				1%	18%	52%
Ibuprofen (HTS 2916391500)	32	38	67	23	26	63
Share				71%	68%	95%
O-acetylsalicylic (aspirin) (HTS291822)	16	16	16	4	3	5
Share				24%	16%	31%
Acetaminophen (HTS 2924296210)	22	18	8	7	4	6
Share				30%	22%	74%

Source: Authors using USITC dataweb

In 2019, 74% of Vitamin C imported by the United States came from China. However, contrary to what was observed with the other API components, that share has decreased over the last ten years (Table 13).

Table 13
United States imports of Vitamin C (HTS number 293627)
(in million dollars)

	Total US imports			China		
	2009	2014	2019	2009	2014	2019
US Imports	328	147	148	286	114	110
Share				87%	78%	74%

Source: Authors using USITC dataweb

The increasing dominance of China as an API producer has been raising concerns for several years. With growing pressures to provide affordable medications and smaller profit margins, obtaining less expensive APIs became a critical element for generic drugs to be competitive (Laurent, 2020). In 2019,

Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) testified in the U.S. Congress that in recent years drug manufacturing has gradually moved out of the United States, particularly in the case of APIs. Woodcock concluded that this was to a large extent due to lower production costs related to electricity, coal, labor and water as well as environmental standards. Furthermore, Woodcock stated that “both China and India enjoy a labor cost advantage and that API manufacturing in India can reduce costs for U.S. and European companies by an estimated 30 percent to 40 percent.”

Dependency on APIs from China: an issue of national security in the United States and beyond
The gradual but growing dependency of the United States on APIs from China that has been a serious concern from a public health point of view for some time has progressively become a national security concern as well, as materialized in the following expression of both governmental and industry experts.

Representatives Anna Eshoo and Adam Schiff, both Democrats from California wrote in September 2019⁶ that the growing dependency on active ingredients from China and the fact that China has a virtual monopoly on key ingredients for critical drugs constitute a national security concern:

"There is no single accounting of the percentage of active ingredients in U.S. drugs that are manufactured in China, but it's significant and growing. The Food and Drug Administration has said approximately 80 percent of active-ingredient manufacturers are located outside the United States, and for some key drugs, China is the only supplier. For instance, China produces the ingredients found in almost every antibiotic and blood pressure medicine and hundreds of other drugs. Thus, China has a virtual monopoly on the ingredients required to manufacture critical medicines. The supply chain already poses a significant public safety issue due to the quality deficiencies that keep arising in the manufacturing of drugs overseas — but the problems run deeper. Depending on any single supplier for such lifesaving goods would be troubling, but when that supplier is China at a time of rising tensions and conflict, it's a national security issue that demands the attention of the administration and Congress."

Thus, if there are disruptions in the production of APIs, it would be impossible for companies to manufacture the final product needed by consumers.

Moreover, Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) testified at the 30 October 2019 hearing held by the Subcommittee on Health of the U.S. House Committee on Energy and Commerce, on “Safeguarding Pharmaceutical Supply Chains in a Global Economy”. In her testimony two things were clear: a) China was significantly increasing the production of APIs and b) the FDA has limited data to provide a full picture of the country's dependency on China for APIs. Indeed, Dr. Woodcock stated that as of August 2019, only 28% of the manufacturing facilities making APIs to supply the U.S. market were in the country. The remaining 72% of the API manufacturing plants supplying the U.S. market were located overseas and 13% were in China. She also provided a chart about the percentage of API manufacturing facilities for all drugs by country or region highlighting an important

trend in this data with regards to China: “FDA’s data show that the number of registered facilities making APIs in China more than doubled between 2010 and 2019.”⁷

Furthermore, Dr. Woodcock added that “although CDER can describe the locations of API manufacturing facilities, we cannot determine with any precision the volume of API that China is actually producing, or the volume of APIs manufactured in China, that is entering the U.S. market, either directly or indirectly by incorporation into finished dosages manufactured in China or other parts of the world.”

The dependency of the United States on APIs from China was also identified as a risk by national security experts. Christopher Priest, Deputy Assistant Director, Healthcare Operations at the Defense Health Agency testified on the military health system before the U.S.-China Economic and Security Review Commission on July 31, 2019 in the following terms:

“The national security risks of increased Chinese dominance of the global API market cannot be overstated. Pharmaceuticals that are crucial to DoD’s ability to promote the health of its Warfighters and protect them from nuclear, biological and chemical threats. Should China decide to limit or restrict the delivery of APIs to the U.S. it would have a debilitating effect on U.S. domestic production and could result in severe shortages of pharmaceuticals for both domestic and military uses. Our concern is the ability of the domestic manufacturing capability to adjust to that risk, alternate sources, if any, and how long those solutions would take to produce results.”⁸

Furthermore, Priest also stated that the Defense Health Agency (DHA) “expects the trend toward Chinese dominance of global API to follow past trends and increase over the next five years.” And consistent with Dr. Woodcock’s testimony, Priest added that given that there is no required registry for API sources it is extremely difficult to assess the extent of the risk.

In November 2019, the U.S-China Economic and Security Review Commission released its annual report which highlighted the United States’ growing reliance on Chinese-manufactured pharmaceuticals and China’s role as a global “active pharmaceutical ingredient” producer.

⁷ While the percentages regarding facilities may show a relatively small dependency on APIs from China (13%) this may be misleading as there are a number of elements that are unknown. Indeed, while the finished pharmaceutical products may come from a country, their APIs may originate in another one. For example, according to the Trade Promotion Council of India (TCPI), India imports 70% of its API requirements from China so while a final product may be from India, it relies on another country to source the active ingredient. CATR, (Centre for Advance Trade Research), “API dependence: Indian pharma’s health hazard”, February 20, 2020. Dr. Woodcock also lists a number of significant limitations in this data:

- “Facilities listed in the Catalog may or may not be producing APIs. Including a facility in an application or the registration and listing process does not require a facility to produce API. Producing an API at the facility, or not producing it, is a business decision made by the company.
- Manufacturers are not required to report to FDA whether they are actually producing an API at a facility, and if they are, the volume of producing it.

APIs made in listed facilities may be used in drugs for both the U.S. and other markets, and some APIs distributed in the United States are subsequently formulated into finished dosage forms (FDF) that are then exported.

Some FDF applications list more than one API supplier in the application. FDA has no visibility into which API supplier an FDF manufacturer uses at any given time.

CDER has limited information about API suppliers for products that do not need an approved application from FDA to be marketed, such as compounded and OTC monograph drugs. API suppliers for such products may not register their facility with FDA if they are sending material to a drug product manufacturer outside the United States to make the FDF, which is then sold in the United States.”

Additionally, in a bipartisan letter to the Secretary of Defense Mark Esper dated December 5, 2019, Senators Warren (D-MA), Kaine (D-VA), Cotton (R-AR) and Romney (R-UT) raised concerns over the U.S. “growing reliance” on drug products made in China and requested further information to better understand the potential risks that the U.S. may confront for this reliance. Indeed, the senators stated:

“Last week, the Commission released a report highlighting the United States' growing reliance on Chinese-manufactured pharmaceuticals and China's role as a global "active pharmaceutical ingredient" producer. Active pharmaceutical ingredients (APIs) are the raw chemical components of drugs that "furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease." APIs are requisite to manufacture pharmaceutical products, including generic drugs and vaccinations. Despite the critical role of APIs in drug production an estimated 80 percent of APIs used in domestic pharmaceutical production originate in foreign nations—predominantly China.”

Rosemary Gibson, author of "China Rx: Exposing the Risks of America’s Dependence on China for Medicine", testified before the Senate Committee on Small Business and Entrepreneurship in March 2020 in very blunt terms:

“The United States faces an existential threat posed by China’s control over the global supply of ingredients in thousands of essential generic medicines.”

Gibson also stated that “[m]edicines in the hands of an adversary can be weaponized.”

With regards to the Coronavirus, she testified that “90 percent of the chemical ingredients for generics in the U.S. to care for people with serious coronavirus infections and are hospitalized are sourced from China. Sedatives, antibiotics, anti-inflammatories, and medicines to raise blood pressure are among the medicines used to care for people with severe coronavirus. China produces 90 percent of the chemical ingredients for these essential medicines.”

In a recent speech, Attorney General Barr recognized that “China is now the world’s largest producer of active pharmaceutical ingredients” and addressed the national security risk that this presents for the United States when he stated that as one Defense Health Agency official had noted, “[s]hould China decide to limit or restrict the delivery of APIs to the [United States],” it “could result in severe shortages of pharmaceuticals for both domestic and military uses.”⁹

Thus, the biggest concern with regards to China and the supply of drugs lies in the supply of APIs and some antibiotics and vitamins.

European Union’s concerns regarding API quality and availability

The United States is hardly alone in its quest about enhancing the security and oversight of the global manufacturing chain. In November 2019, the European Commission, Health and Food Safety Directorate-General published a document which states that “[o]ne of the priorities identified by the Pharmaceutical Committee in its working program is to enhance the security and oversight of the global

⁹ Transcript of Attorney General Barr’s Remarks on China Policy at the Gerald R. Ford Presidential Museum, Grand Rapids, MI ~, July 17, 2020

manufacturing chain.” According to the document, “[t]he availability of APIs of high quality for manufacturing of medicinal products for the EU market is a growing concern” and “manufacturing issues, often related with the API quality, are one of the major reasons of shortages of medicinal products in the EU.”

The document also states that with regards to “the EU dependency on API in China, DG SANTE initiated a dialogue with GROW (the Commission’s Directorate-General for Internal Market, Industry, Entrepreneurship and small business) to explore the possibility of facilitation production of the API in Europe.” With this purpose, SANTE and GROW organized a meeting in December 2019. As in the case of the United States, this concern was raised before the outbreak of Covid-19, but the health crisis put in further evidence the supply chain bottlenecks that Europe could face as a result of shutdowns of Chinese factories (Laurent, 2020).

France’s National Pharmaceutical Academy estimates that the EU imports 80% of its APIs mostly from China and India. The U.K. medicines regulator, the Medicines and Healthcare Products Regulatory Agency (MHRA,) estimates that about 40% of all APIs are produced in China (Laurent, 2020). Based on a paper prepared in March 2020 by the pharmaceutical committee of the European Commission, China provides 75% of the APIs used in the formulations of drugs in the National List of Essential Medicines (NLEM). (Vibha et al.2020)

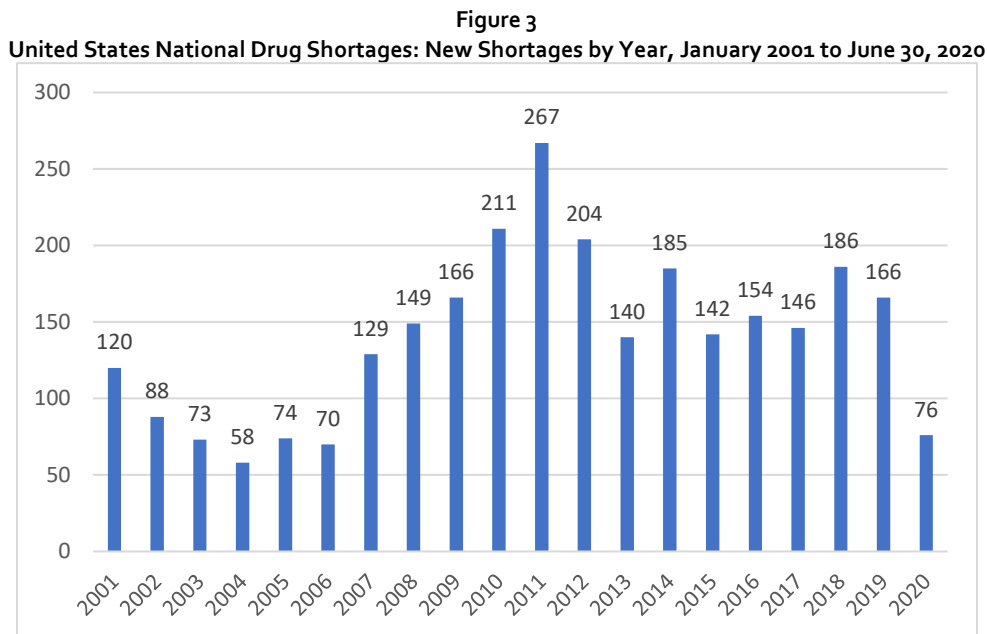
The case of India

India is also considered to be relying significantly on APIs manufactured in China (Horner, 2020, Laurent, 2020, Balfour, 2020). Indeed, its reliance on China has been an issue of debate within the Indian government for a while. In 2014 Motilal Vora, member of the Indian Parliament, spoke about the inappropriateness of importing APIs from a single country. Also in 2014 Ajit Doval, National Security Advisor in India called the increasing dependency on Chinese drug makers a “national threat.” (Vibha et al.2020) In 2018, a Parliamentary Committee indicated that among the concerns regarding the dependency on Chinese API were the significant increases in prices during the previous two years (1,200 %). (Vibha et al.2020) And even before Covid-19 the Pharmaceutical Export Promotion Council of India (Pharmexcil) indicated that it was working on a plan to reduce the country’s reliance on imported APIs and has recently decided to launch a number of incentives to increase the local production of APIs. (CPhi, 2019) In March 2020, the Indian government announced a plan to promote domestic manufacturing of critical key starting materials/drug intermediates and active pharmaceutical ingredients in the country.¹⁰ Based on the European Pharmaceutical Review, Indian manufacturers grew their dependency on APIs from China from importing about 0.3% in 1991 to procuring currently about 70% of the APIs by volume.

Consistent with this, a study conducted by the European Fine Chemicals Group /CEFIC in 2008 shows that while in the 1980s the origin of APIs for the EU market was 80% from the EU and 10% from China and India in terms of volume, by 2008 this had changed to 20% from the EU and between 70-80% from China and India. Based on the same source, this trend was consistent in other parts of the world apart from the United States where the Chinese/India API market was about 50% and growing. (Dadhich, 2020)

¹⁰ India, Cabinet approves Promotion of domestic manufacturing of critical Key Starting Materials/Drug Intermediates and Active Pharmaceutical Ingredients in the country, March 21, 2020 accessed at <https://pib.gov.in/PressReleasePage.aspx?PRID=1607483>

So far the drug supply chain has been resilient and there has not been an increase from previous years on drug shortages as a result of Covid-19. Indeed, a chart prepared by the American Society of Health-System Pharmacists (ASHP) does not indicate a rise in shortages in the United States in 2020.



Source: ASHP

During a brief time at the beginning of the Covid-19 crisis there were additional concerns when India decided to restrict the export of 26 pharmaceutical products (13 APIs and 13 formulations made from those APIs).¹¹ Based on reports, the Indian government took this measure because Indian manufacturers rely heavily on imports of APIs from China. (Balfour, 2020) Yet this has not been reported as much given two important factors that make India a reliable partner of medicines for the U.S. Firstly, many Indian companies have invested heavily in the United States market acquiring a number of companies and given that their future is linked to maintaining a secure drug supply chain they would be the first ones to resist any future government export restrictions as they have become a critical strategic ally for the U.S. Secondly, the pharmaceutical industry is a strategic industry for India and therefore, the government needs to make sure not to make the same mistake in the future as it would otherwise hurt the perception of India's reliability as a drug supplier. The combination of both factors makes India a much-trusted ally with regards to the drug supply chain.

While the supply chain has held up, countries and companies are exploring alternatives to ensure a stronger supply chain with less vulnerabilities with regards to China and its lower prices. In this sense, countries around the world are brainstorming to identify additional potential vulnerabilities in the drug supply chain as well as looking at different options to configure a new drug supply chain providing a greater degree of certainty but the challenge is to do so without raising drug prices.

¹¹ India, Directorate General of Foreign Trade, Notification 50 2015/2020, March 3, 2020.

Proposed solutions

In the United States, there have already been several initiatives to bring back drug manufacturing to the country. The United States Trade Representative (USTR) under the Trump Administration called for a post-pandemic industrial policy that could include increased tariffs and subsidies to reshore certain supply chains (Lighthizer, The Economic Club of New York, 4 June 2020) and on 24 February 2021 President Biden signed an Executive Order to help create more resilient and secure supply chains for critical and essential goods. The order directs an immediate 100-day review across federal agencies to address vulnerabilities in the supply chains of four key products, including pharmaceuticals and active pharmaceutical ingredients (APIs). This work will complement the ongoing work to secure supply chains needed to combat the COVID-19 pandemic.

Although minimizing the risks of medical supplies, drugs and food shortages to these kinds of shocks is desirable and falls within the realm of public policy and the need for a public response is evident, the decisions regarding location of production, suppliers and distribution logistics are made at the firm level. Moving production often requires significant investments and usually responds to years-long-strategic plans by industries. To compel firms and industries to change those decisions governments may need to bear at least some of the costs. For the Latin America and the Caribbean region closer collaboration with the United States in those efforts may be critical to seize the opportunities those changes may open.

In this sense, the cost of prescription drugs is a critical element that must be weighed in even by countries with high purchasing power like the U.S., those in the European Union and others. Policies should seek to reduce the national security risk posed by reliance on critical drugs that today are being sourced from China (either APIs or finished products) while looking for a realignment of the drug supply chain that must be secure, cost-effective and sustainable. Thus, the solution should be found at the intersection of national security factors and the need to ensure the affordability of drugs.

This is particularly true with regards to generic drugs that have been critical to ensure access to medicines around the world. In the United States, where 9 out of every 10 drugs consumed is a generic, these drugs have been of paramount importance in generating savings which totaled US\$313 billion in 2019, with 10-year savings amounting to nearly US\$2.2 trillion. (Association for Accessible Medicines, 2020) But generic drugs have increasingly lower profit margins and therefore, in order to ensure the sustainability of the generic industry, policy changes that would affect the drug supply chain have to provide options to allow low production costs. Bringing back all drug manufacturing is, in the opinion of many, unrealistic and would put at risk the sustainability of the generic industry. (Packard et al, 2020, Reuters, 2020, Lowe, 2020)

Is there an opportunity for Latin America?

The global use of medicines has continued to grow during the past 10 years including for non-communicable diseases which in 2016 were responsible for 71% of deaths around the world. (Aitken, 2020) The global pharmaceutical market reached total sales of US\$1.25 trillion in 2019, of which U.S. sales were US\$510 billion. According to IQVIA's annual report of March 23, 2020, the global market for medicines is expected to continue growing through 2024 to reach between US\$1.57 and US\$1.6 trillion of gross revenue. However, efforts to constrain drug spending by governments and payers and the fact

that many patents or exclusivities will expire in the next five years are expected to slow down growth. (Terry, 2020)¹²

Therefore, this is a growing global market where price pressures are increasing and where the pharmaceutical industry operating in Latin America could play an important role in the realigned drug supply chain by providing APIs and finished drugs to markets such as the United States, the European Union and Japan.

Some of the areas identified by IQVIA as global health priorities are diabetes, respiratory, cardiovascular and cancer treatments. (Aitken, 2020)

The Latin America pharmaceutical market and industry

Latin America has traditionally had a significant pharmaceutical industry, in countries such as Argentina, Brazil, Chile, Colombia and Mexico. The fact that three out of the five countries AstraZeneca has made agreements to produce the coronavirus vaccine are from Latin America: Argentina, Brazil and Mexico, attest to this assertion.

According to data from Sindusfarma, in 2019 in Brazil there were 249 registered laboratories of which 101 (41%) are of international origin and 148 nationally owned (59%). In the Pharmacy Channel, multinational companies hold a 51.6% stake of the market in terms of invoicing and 34% in units sold (boxes). Domestic laboratories account for 48.4% of the market in invoicing and 66% in units sold (boxes). The ever-growing share of generic medication has given national companies the leadership in sales per units. The Brazilian pharmaceutical industry ended the year of 2018 with 96.744 thousand direct jobs, being that 3.392 employed by the companies that manufacture pharmaceutical preparations, 10.072 in companies that manufacture medication for veterinary use and 83.280 in companies manufacturing medication for human use, according to official data(Sindusframa, 2020).

Based on information from the Mexican National Chamber of the Pharmaceutical Industry (CANIFARMA) the pharmaceutical industry in Mexico represents about 1.2% of the Mexican GDP and 7.2% of the manufacturing GDP. In terms of jobs, based on information from a report from KPMG the pharmaceutical industry generates about 74,000 direct jobs and about 310,000 indirect jobs (KPMG in Mexico, 2017). Mexico is also the largest exporter of pharmaceuticals in the region (US\$1.1 billion in 2017¹³). The Mexican pharmaceutical industry is comprised by 74.7% of patented drugs, 12.1% by generic drugs and 13.2% on OTC based on information from CANIFARMA. CANIFARMA is expecting that the generic market share will grow in the future. The Mexican pharmaceutical market is expected to continue to grow particularly in drugs for the treatment of non-communicable diseases such as diabetes, cardiovascular disease, cancer and mental and behavioral disorders¹⁴.

Argentina, the third largest Latin American market, has about 229 industrial plants of which 181 are locally owned. The pharmaceutical industry is responsible for 43,000 direct jobs in Argentina and 120,000 indirect jobs. About 71.5% of consumed drugs in Argentina are locally manufactured while the remaining 28.5% is imported. (CILFA, 2019)

¹³ BMI Pharmaceuticals & Healthcare Report, Mexico Pharmaceuticals & Healthcare Report, Mexico Pharmaceutical Trade Forecast - Industry Forecast; May 17, 2019.

¹⁴ BMI Pharmaceutical and Healthcare Report, Mexico Pharmaceuticals & Healthcare Report, Market Overview, March 6, 2019.

Colombia has 91 establishments authorized by regulatory agency INVIMA to produce medicines and biological products. According to SISMED data provided by the Cámara de la Industria Farmacéutica, in 2018 the national manufacturing of medicines accounted for 69% of units, while 31% of drugs were imported. In terms of value, nationally produced drugs accounted for 35% and imported drugs for 65%. However, Colombia has experienced a contraction of locally owned companies. (ANDI, 2018)

Chile has 180 pharmaceutical companies. This industry has experienced a strong growth during the past decade. According to a recent SOFOFA study, the industry accounts for 14,884 direct jobs each year, equivalent to 2% of the manufacturing industry and 0.22% of annual-effective jobs. (Carrasco et al, 2020) The share of the Chilean pharmaceutical industry in GDP is about 1.2% while pharmaceutical exports represent 1.1% of the total manufacturing industry. This market is expected to continue growing at a pace of 6-7% driven by drugs for rare diseases, diabetes, obesity, HIV, COPD, cancer and immunostimulants. Chile is also becoming an emerging market for clinical research (0.34 studies per 10,000 inhabitants). It is estimated that multinational laboratories invest about US\$30 million per year in clinical trials in this market involving about 6,500 Chilean patients and 1,400 researchers. (Invest in Chile, 2019)

United States Imports of Pharmaceuticals from the region

On the demand side, the Latin American pharmaceutical market is growing significantly. In the period 2008 to 2017 it doubled from US\$34.6 billion to US\$69.11 billion.¹⁵ and also has some of the largest pharmaceutical markets in the world such as Brazil (#7) and Mexico (#15). (Aitken, 2020) In addition, Latin America includes several pharmerging markets. Pharmerging markets are defined as countries with per capita income below \$30,000 per year and five-year absolute growth in pharmaceutical spending greater than US\$1 billion. IQVIA identified for 2019 a total of 22 countries in the world as pharmerging. Latin America includes 5 of the 22 countries: Argentina, Brazil, Chile, Colombia, and Mexico. (Aitken, 2020)

The population in Latin America is aging quickly. In 2018, 11% of the population in the region was over 60 years old. While at the time this was lower than in other regions, such as Europe (23.9%) or North America (20.8%), it is expected to grow to 17% by 2030 and to 25% by 2050. (IADB Blog, May 7, 2018)¹⁶ Some countries like Brazil, Chile, Colombia, and Costa Rica will age faster. And with an aging population, the demand for pharmaceuticals will increase as well as for the need for chronic therapies such as insulin for diabetic patients. The use of biosimilars is also expected to grow.

This means that the Latin American market will be an increasingly attractive market for pharmaceutical companies and governments, insurances and consumers will be under significant pressure to contain the additional health expenditures expected in the years to come.

According to BMI Pharmaceuticals and Healthcare reports statistics, an increasing dependency on drug imports is observed in the region. Data on exports and imports of pharmaceuticals in the region during the period 2008-2018, shows that while exports have been growing for most top Latin American pharmaceutical markets (Argentina, Brazil, Chile and Colombia), imports have been growing considerably faster for the five top countries including Mexico in this category too.

¹⁵ Statista, Pharma industry market value LatAm.

Taking into consideration all the information mentioned above, namely a) the need to diversify the drug supply chain that has become reliant on China, b) the fact that while there is likely to be some additional drug manufacturing in the U.S. and the EU, production costs are considerably higher, c) the need to continue providing pharmaceutical products at accessible prices, d) the fact that several Latin American markets are pharmerging and therefore valuable future pharmaceutical markets and that several of them already count with important pharmaceutical industries, this could lead to an adjustment of the pharmaceutical industry in Latin America so that it also becomes part of the drug supply chain of developed countries such as the United States, the European Union, Japan and Australia among others.

However, to realize this unique potential, Latin American governments will need to identify the pharmaceutical industry as a strategic sector as other countries have done and pursue policies that will help companies reach their potential. On the other hand, today most of the pharmaceutical exports from Latin America are directed to the rest of the region. In order to expand exports to developed countries, companies will need to conduct the necessary work to get the approvals to register their products by regulatory agencies such as the U.S. Food and Drug Administration, the European Medicines Agency and Australia's Therapeutic Goods Administration. This will represent an adjustment that companies will need to embrace.

Looking forward

Bringing manufacturing back has been in the United States purview for some time, especially because of the fall in manufacturing employment observed during the last three decades that is often linked to the deterioration in the quality of life of significant sectors of the population. The growing dependency on China for APIs and the outbreak of the new coronavirus disease has brought lawmakers in both chambers and in both parties to push for legislative efforts to bring back production and strengthen U.S. supply chains of critical products.

The trade war with China and calls to “decouple” the United States economy from the Asian country had already prompted manufacturers to reconsider their presence in China. Untangling supply chains that were built up over long periods of time and based on strategic considerations of business development is a complex and difficult task. The US-China trade war and rising wages in China had already incentivized some multinationals to relocate their supply chains away from China to other parts of Asia; the textile sector was an early example of this trend. (The economist, 2020)

In 2019, for the first time, A.T. Kearney produced what they called the near-to-far trade ratio (NTFR) that tracks the movement of United States imports toward nearshore production from Mexico. This index looks at the ratio of annual total Mexican manufactured imports to the United States to the value of manufactured imports from the 14 Asian countries. While this ratio had stayed stable over the past 7 years at between 36% and 38%, in 2019 it rose to 42%. That is, it went from about 37 cents of Mexican imports to the dollar of Asian imports to 42 cents to the dollar. Although A.T. Kearney, research shows that as early as 2016 more than half of U.S. companies with manufacturing operations in Mexico had moved production there from other parts of the world (including China), to serve the U.S. market, some of last year's growth in Mexico-to-U.S. manufacturing imports may have resulted from the transshipment of goods to circumvent tariffs.

The realization of the fact that globalization and efficiency have led to the concentration of drug suppliers, particularly of APIs, has drawn attention to the potential vulnerabilities of the drug supply chain. Countries around the world are currently brainstorming about ways to reduce their overdependency on China. As a result of this process there is likely to be a combination of some reshoring of some drug manufacturing along with diversification and near-shoring. This diversification will be critical to ensure multiple production sites that reinforce the resilience of the drug supply chain if one or two countries with important manufacturing centers face problems thus safeguarding a strong and reliable drug supply chain. It will also ensure lower production costs, critical to provide access to affordable medications which is one of the top priorities of most countries. Global companies operating in Latin America can also see this as an opportunity for further growth in important pharmerging markets. If Latin American governments adopt the right policies to support the industry, they could see an important increase in new investments in the sector.

This represents a unique opportunity for the pharmaceutical industry operating in Latin America which is well positioned to play a larger role as a global drug supplier, not just in the developing world but also in developed countries with higher purchasing power. This could lead to important economic growth for the countries involved and also reduce their increasing dependency of APIs and finished dosage form as in the last years they have experienced a significant growing trade deficit. This is of particular importance considering that many of these countries have weak currencies compared to the U.S. dollar and a quickly aging population.

But this opportunity will not be realized if Latin American governments do not make the necessary policy adjustments to support the international growth of their pharmaceutical industries and companies do not make the necessary changes and adjustments to secure the marketing approval of their products by regulatory agencies such as the Food and Drug Administration in the United States or the European Medicines Agency. Companies will also need to adjust their business models. And while the realignment of the global drug supply chain will take some time, the window of opportunity will not last long. Latin America has to move quickly and decisively sending the right message to decision makers (both in the public and private sectors) that Latin America is indeed part of the solution to ensure the availability of quality and affordable drugs through a diversified supply chain that is secure and resilient.

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Appendix

Table A.1
HTS codes and descriptor of Pharmaceuticals and Antibiotics

HTS Code	Commodity Description
300510	ADHESIVE DRESSINGS AND OTHER ARTICLES HAVING AN ADHESIVE LAYER
294190	ANTIBIOTICS, NESOI
300219	BLOOD FRACTIONS, NESOI WHETHER OR NOT MODIFIED OR OBTAINED BY MEANS OF BIOTECHNOLOGICAL PROCESSES
294140	CHLORAMPHENICOL AND ITS DERIVATIVES; SALTS THEREOF
294150	ERYTHROMYCIN AND ITS DERIVATIVES; SALTS THEREOF
300650	FIRST-AID BOXES AND KITS
300670	GEL PREPARATIONS FOR USE IN HUMAN AND VETERINARY MEDICINE AS LUBRICANT FOR OPERATIONS OR PHYSICAL EXAMS OR AS A COUPLING AGENT B/W BODY AND MEDICAL IN
300190	HEPARIN AND ITS SALTS; OTHER HUMAN OR ANIMAL SUBSTANCES PREPARED FOR THERAPEUTIC OR PROPHYLACTIC USES, NESOI
300214	IMMUNOLOGICAL PRODUCTS, MIXED, NOT PUT UP IN MEASURED DOSES OR IN FORMS OR PACKINGS FOR RETAIL SALE
300213	IMMUNOLOGICAL PRODUCTS, UNMIXED, NOT PUT UP IN MEASURED DOSES OR IN FORMS OR PACKINGS FOR RETAIL SALE
300211	MALARIA DIAGNOSTIC TEST KITS
300390	MEDICAMENTS (EXCLUDING VACCINES, BANDAGES AND PHARMACEUTICAL GOODS) NESOI, OF TWO OR MORE MIXED CONSTITUENTS, NOT IN MEASURED DOSES, ETC.
300449	MEDICAMENTS CONTAINING ALKALOIDS OR DERIVATIVES THEREOF, NESOI, PUT UP IN MEASURED DOSES OR IN FORMS OR PACKINGS FOR RETAIL SALE
300320	MEDICAMENTS CONTAINING ANTIBIOTICS, NESOI, NOT PUT UP IN MEASURED DOSES OR RETAIL PACKINGS
300460	MEDICAMENTS CONTAINING ANTIMALARIAL ACTIVE PRINCIPLES DESCRIBED IN SUBHEADING NOT 2 CH 30, IN MEASURED DOSES, FOR RETAIL SALTE
300360	MEDICAMENTS CONTAINING ANTIMALARIAL ACTIVE PRINCIPLES DESCRIBED IN SUBHEADING NOT 2 TO THIS CH 30
300310	MEDICAMENTS CONTAINING PENICILLINS OR DERIVATIVES THEREOF, OR STREPTOMYCINS OR THEIR DERIVATIVES, NOT IN MEASURED DOSES OR RETAIL PACKINGS
300490	MEDICAMENTS, IN MEASURED DOSES, ETC. (EXCLUDING VACCINES, ETC., COATED BANDAGES ETC., AND PHARMACEUTICAL GOODS), NESOI
300420	MEDICAMENTS, IN MEASURED DOSES, ETC., CONTAINING ANTIBIOTICS, NESOI
300410	MEDICAMENTS, IN MEASURED DOSES, ETC., CONTAINING PENICILLINS OR DERIVATIVES THEREOF, OR STREPTOMYCINS OR THEIR DERIVATIVES
294110	PENCILLINS AND DERIVATIVES WITH A PENICILLANIC ACID STRUCTURE; SALTS THEREOF
294120	STREPTOMYCINS AND THEIR DERIVATIVES; SALTS THEREOF
294130	TETRACYCLINES AND THEIR DERIVATIVES; SALTS THEREOF
300220	VACCINES FOR HUMAN MEDICINE
300590	WADDING, GAUZE, BANDAGES AND SIMILAR ARTICLES, IMPREGNATED OR COATED WITH PHARMACEUTICAL SUBSTANCES FOR MEDICAL, SURGICAL ETC. PURPOSES, NESOI

Source: Authors using USITC and CRS reports to identify the codes

Table A.2
HTS codes and descriptor of Antibiotics and other API ingredients

HTS Number	Product Description
291639	AROMATIC MONOCARBOXYLIC ACIDS, THEIR ANHYDRIDES, HALIDES, PEROXIDES, PEROXYACIDS AND THEIR DERIVATIVES, NESOI
291822	O-ACETYLSALICYCLIC ACID (ASPIRIN), ITS SALTS AND ESTERS
292429	CYCLIC AMIDES (INCLUDING CYCLIC CARBAMATES) AND THEIR DERIVATIVES, AND SALTS THEREOF, NESOI
293627	VITAMIN C (ASCORBIC ACID) AND ITS DERIVATIVES, UNMIXED
294110	PENCILLINS AND DERIVATIVES WITH A PENICILLANIC ACID STRUCTURE; SALTS THEREOF
294120	STREPTOMYCINS AND THEIR DERIVATIVES; SALTS THEREOF
294130	TETRACYCLINES AND THEIR DERIVATIVES; SALTS THEREOF
294140	CHLORAMPHENICOL AND ITS DERIVATIVES; SALTS THEREOF
294150	ERYTHROMYCIN AND ITS DERIVATIVES; SALTS THEREOF
294190	ANTIBIOTICS, NESOI

Source: Authors using USITC and CRS reports to identify the codes

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