Supply chain management of medicines and other health technologies during a health emergency response

Leveraging national experiences from Latin America and the Caribbean during the COVID-19 pandemic

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María Luz Pombo and Tomas Pippo, Advisors, Medicines and Health Technologies Unit, PAHO/WHO, supervised the preparation of this publication. Iván Redini was in charge of the overall coordination of the project. Nicolás Dvoskin, Natalia Jorgensen, Pablo Macadam, Alexandra Mata, and Iván Redini constituted the core working group in charge of study design, field research, and implementation. The technical input of the following PAHO technical officers contributed greatly to the development and review of the study: Pablo Alcocer Vera, Francisco Caccavo, Mariela Canepa, José Luis Castro, Murilo Freitas, Alexandre Lemgruber, and Edgard Rojas. Finally, sincere thanks go to James Fitzgerald, Director, Department of Health Systems and Services, PAHO, and Analia Porras, former Chief, Medicines and Health Technologies Unit, PAHO, for their support.
Introduction

The purpose of this document is to provide insights to decision makers and health practitioners for better preparation and adequate management of future pandemics, so they can capitalize on the experience and knowledge acquired during COVID-19. It compiles experiences from Latin American and Caribbean countries, in particular including cases from Argentina, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, Guatemala, Haiti, Jamaica, México, and Paraguay. Lessons learnt from activities, coordination, and achievements under COVID-19 circumstances are extracted for the purpose of contributing to a discussion for the preparation against future pandemic crises.

The document analyzes the management of medicines and other health technologies (MHT), including pharmaceuticals, vaccines, in vitro diagnostic tests (IVDs), personal protective equipment (PPE), and other medical devices required for the emergency response. Following PAHO’s core components for pandemic preparedness, the document is structured in four sections:
1. COVID-19 situation in Latin America and the Caribbean

As per Figure 1, from the onset of the global COVID-19 pandemic in February of 2020, to October of 2022, the number of new cases of the disease was 626,337,158 and the number of cumulative deaths was 6,566,610 globally. Latin America and the Caribbean region were especially impacted; although the region has 8.4% of the world population, it registered 12.7% of total cases and 26.6% of total deaths.

In this context, a collective effort was focused on reducing and controlling the incidence of SARS-CoV-2 infection and its effects. These efforts included prevention, diagnosis, and treatment of the disease to reduce its morbidity and mortality. The available tools have been relevant to reduce severity, save lives, and prevent deaths. Therefore, the availability of medicines and other health technologies (MHT) for emergency response became a priority for all Pan American Health Organization (PAHO) Member States.

After the outbreak of COVID-19, governments developed strategies including interventions that could guarantee directly and indirectly the normal functioning of the supply chains of COVID-19 essential medicines and other health technologies, such as:

- **Medicines** including pharmaceuticals and vaccines not only to respond to COVID-19 but to maintain proper operation of national programs.
- **Medical supplies** refers to consumables for hospital and laboratory use (alcohol, syringes, gauze, oxygen, hand sanitizers, surgical gowns, boots and clogs, surgical caps, goggles, among others).
- **Medical devices** including equipment and technologies, covering in vitro diagnostic tests, personal protective equipment, face masks, face shields, examination gloves, surgical gloves, among others.

The demand for essential medicines and other health technologies increased exponentially in a short period of time, while supply remained limited, provoking disruptions in national supply chains, particularly in middle and low-income countries. Product shortages were observed in some countries in Latin America.

1.1. Preparedness framework for emergency response

One of the most significant preparedness developments is the International Health Regulations (IHR), adopted by the 58th World Health Assembly in 2005. These regulations constitute a legally binding agreement of 196 countries to build the capability to detect and report potential public health emergencies.

worldwide. IHR requires that all countries could be able to detect, assess, report, and respond to public health events. By the time the COVID-19 pandemic started, most Latin American countries had adopted the IHR regulatory framework.

To face emergency pandemics, the World Health Organization (WHO) developed a framework of five interactive subsystems of preparedness, readiness, and response coordination (Figure 2). All five core components and the connection between them were essential to an effective COVID-19 response. This study focuses on essential products procurement and supply chains, centering the attention on components 1 and 5, which are preparedness and response coordination, and equitable access to essential supplies, since these are central elements to ensure health systems have prepared medical supply systems during emergencies.

The degree of country preparedness planning and the robustness of their health systems are important determinants of pandemic response outcomes. While they are not the unique aspects that ensure timely access to essential supplies in emergencies like COVID-19, national emergency preparedness and response planning is critical to ensure access to essential supplies.

From a technical standpoint, it is recommended that all pandemic preparedness plans include the dimensions presented in Figure 3. These are the dimensions that need to be evaluated and monitored for adequate country preparedness.

International organizations have been advising and supporting countries towards developing preparedness plans to achieve long-term improvements in country readiness and public health systems, performed through building capabilities for evaluating threats and their readiness capacity, engaging leaders, increasing political will, and building knowledge.
1. COVID-19 situation in Latin America and the Caribbean

1.2. Equitable access to essential supplies

The pandemic has exposed critical inequalities in global medicines and other health technologies (MHT) supply chains. From the early stages of the COVID-19 emergency, the lack of global commitment to equity as a guiding principle for access was a challenge that had to be faced by global collaboration mechanisms, such as the WHO ACT (Accelerator), launched in April 2020 to support distribution of tests, treatments, and vaccines.

Throughout the different stages of the pandemic, low- and mid-income countries were affected by limited MHT for emergency response. In some cases, export banning from manufacturing countries left patients and healthcare workers without sufficient supplies. Power disparities imply inequities, putting at risk those countries that lack access to resources, creating difficulties to manage emergency situations (5).

The health crisis has also revealed the dependence of Latin America and the Caribbean on imports of MHT from outside the Region, the vulnerability of global supply chains in emergencies, and the high heterogeneity in terms of regional capacities for research, development, and production of health technologies. The strengthening of regional capacity for the development and production of MHT and its raw materials is important for improving their accessibility, and adequately responding to regional health needs, especially during health emergencies, which also contributes to health security and economic and social development.

To provide a common and sustainable framework with prioritized strategic lines of action to guide the countries of the Region, in 2021 PAHO Member States adopted the policy document “Increasing production capacity for essential medicines and health technologies” and its corresponding resolution CD59.R3. Under this framework, PAHO launched the “Regional Platform to Advance the Manufacturing of COVID-19 Vaccines and other Health Technologies in the Americas,” which brings together public and private actors to encourage the development and manufacturing of essential and strategic health technologies in the Americas (6).

In this line, equitable access to diagnostic testing is an example of a key tool to control COVID-19 outbreaks. Tests allow the identification of infected individuals and enable isolation of infected ones and tracing of their contacts (7) cost-efficiently. One of the first critical interventions in the pandemic response was installing lab capacity to detect cases and isolate them to avoid the spread of the disease.

Although in early 2021 all countries in the Region had testing policies, only a few countries had open public testing for anyone showing COVID-19 symptoms and testing available to asymptomatic people (Graph 1a).

By the end of 2021, most countries broadened their testing policies (Graph 1b), portraying the importance of an adequate and coordinated laboratory response.

This is the consequence of the relevance that diagnostics had during the COVID-19 emergency response, as one of the means to address the crisis. In this line of work, PAHO/WHO published laboratory technical guidance on SARS-CoV-2 detection during the early stages of the pandemic outbreak, which was included in PAHO’s Epidemiological Updates. This initial guidance was expanded into several documents published and delivered to member countries to support the development of their multi-level detection strategies.

Graph 1a. Testing policies – March 2021

Graph 1b. Testing policies – November 2021

2. Strategic coordination: planning, coordination, and funding

Governments soon realized the importance of having access to essential health products such as respirators, medicines, medical supplies, personal protective equipment (PPE), reagents, and tests, among others. Acquiring them was a major issue at the outbreak of the pandemic.

The standard planning process was crossed by institutional elements that are additional to the strategies and practices implemented in the procurement process in the past, but inevitable in a crisis (see Table 1).

Decision making tended to become more centralized in Latin America during the COVID-19 pandemic, to facilitate coordination and resource allocation. In some countries leadership was taken by the Heads of State, in others by the Ministers of Health. In other countries such as Colombia and Mexico, Crisis Committees also played very important roles in leading the response to the pandemic.

Table 1: Institutional and technical elements for strategic coordination

<table>
<thead>
<tr>
<th>Technical elements</th>
<th>Institutional elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market analysis</td>
<td>Leadership</td>
</tr>
<tr>
<td>Purchasing power consolidation</td>
<td>Emergency declaration</td>
</tr>
<tr>
<td>Supplier relationship</td>
<td>Coordination mechanisms</td>
</tr>
<tr>
<td>Purchase processes</td>
<td>Legal &amp; regulatory policies</td>
</tr>
<tr>
<td>Information &amp; analytics</td>
<td>Border &amp; comex policies</td>
</tr>
<tr>
<td>Transport &amp; warehousing</td>
<td>Special funding (beyond budget)</td>
</tr>
<tr>
<td>Last mile delivery &amp; organization</td>
<td>Communication</td>
</tr>
<tr>
<td>Transparency</td>
<td>Transparency</td>
</tr>
</tbody>
</table>

Source: Dien elaboration

Preparedness planning helps health systems and services to be more resilient and allows for a faster and organized response to reduce and control unexpected negative health events and their consequences. It includes country readiness strengthening, health security preparedness, and epidemic and pandemic preparedness and prevention.1 Although by the time of the pandemic Latin American countries had adopted the International Health Regulations (IHR) regulatory framework, many countries lacked follow through. As of 2018, only one-third of countries had developed the capacities required under the IHR (2005). While progress has been achieved in many higher income countries, low- and middle-income countries struggle with funding these functions. Not only does this impact their own ability to respond to outbreaks, but it also puts the whole world at risk.

Another element to ensure access to essential products and services and to attain equity in the resource’s allocation is coordination at the subnational level. The decision making process in federal countries, such as Argentina and Brazil, involved national and sub-national administrations and was more complex because it required reaching consensus when health decisions were not delegated.

2.1. Planning

Estimating healthcare demand is an initial process that allows planning for required medicines and other health technologies for emergency response to ensure an adequate end-to-end supply chain distribution. This process – estimating performance, expansion, duration, and requirements of the pandemic itself – is complex in periods of high uncertainty, in which the data obtained from the past are no longer enough to predict the future.

The generation of information in real time was important to be able to predict with greater precision and speed and to act accordingly. The fact that the COVID-19 pandemic occurred in the information and technology age generated a very wide dissemination of the different existing models to predict the behavior of the disease, which were developed with different levels of sophistication. The collaboration between local or foreign academic and multilateral institutions and the governments was important. Both WHO and PAHO developed epidemiological and resource prediction tools to support decision making. WHO provided a toolkit to help countries estimate the needs of specific essential products at a macro level (COVID-19-ESFT) (6). There were three product categories on the toolkit: diagnostics, biomedical and PPEs.

PAHO provided a model to estimate PPE demand at the hospital level. Based on a previous H1N1 version this model considers: what PPEs should be used, where, and a theoretical protocol of correct use. It included technical guidelines and specifications (9).

Initially there was no knowledge of what was going to be required, so it was important to provide the logistics units with this technical information to improve calculations and to direct supplier search. PAHO’s hands-on provision of technical support working together with Health Ministries in Latin America was a new dynamic in planning and response coordination. Additionally, decision makers had to analyze existing supply chains, spot weak links in the process, and evaluate the influence of their decisions on provision, in order to minimize disruptions, prioritize investment, and secure the needed vaccines, medicines, and devices in sufficient quantities and on time to avoid health crises. Ongoing monitoring was important to ensure adequate feedback and timely actions to avoid shortages.
2.2. Coordination and funding

International organizations have been working with governments, industry, and the Pandemic Supply Chain Network to boost production and secure allocation for critically affected and at-risk countries.

In the Latin American region procurement required imports from other regions because most countries lack sufficient local production capacity. Four different ways to procure goods were mainly observed:

- direct procurement,
- acquisitions and donations with PAHO support,
- bilateral donations,
- acquisitions and donations with WHO ACT-Accelerator support.

To acquire essential health products, many countries relied on international cooperation and multilateral organizations. The initial disarray in supply chains globally and the disparity in bargaining power between developed countries and smaller LMICs, was instrumental in paving the way to the use of international mechanisms of collaboration for COVID-19-related purchases in low- and middle-income countries.

Regarding joint and international agencies’ acquisitions, WHO, together with GAVI and UNICEF, provided its own mechanisms to provide access to vaccines and other health technologies.

Public-private collaborations — the ACT-Accelerator and the COVAX facility

Launched in April 2020, the ACT-Accelerator initiative (10) is an example of public/private collaboration, whose impact draws on the strengths of its partners and plays a key role to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines. The partnership comprises three pillars (Diagnostics, Therapeutics, and Vaccines), with a Health Systems and Response Connector (HSRC), and a cross-cutting “Access and Allocation” workstream.

The Vaccines Pillar, COVAX (11), supports countries’ needs and own goals to control COVID-19, contributing towards the 70% global vaccination target in 2022. COVAX achieved the delivery of over 1 billion vaccine doses to over 140 countries and territories in less than a year and supported more than 40 countries to start their vaccination campaigns.
In an effort to address COVID–19 and future infectious disease challenges, PAHO has joined the WHO mRNA Vaccine Technology Transfer Hub. Two Latin American vaccine manufacturers were selected as the first global spokes: Bio–Manguinhos Institute, a public manufacturer from Brazil, and Sinergium Biotech, a private company from Argentina. This initiative is currently underway and as appropriate, involves information sharing, training, and technology transfer to establish regional capacities for the development and production of mRNA-based vaccines.

The efforts required to deal with the COVID–19 pandemic implied the use of additional resources to those contemplated in countries’ regular budgets. International financial institutions intervened, providing substantial funds to collaborate with procurement and logistics. Regarding funding in Latin America, PAHO’s Strategic and Revolving Funds financing alternatives were used, among other sources.

In 2021, COVID–19 vaccination supply and logistic guidance was published to help countries develop and strengthen supply chain strategies to receive, store, distribute and manage COVID–19 ancillary products (12).

<table>
<thead>
<tr>
<th>PAHO Procurement Mechanisms in Million USD</th>
<th>2020 Million USD</th>
<th>2021 Million USD</th>
<th>Percentage Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccines, syringes, &amp; cold chain</td>
<td>734 M</td>
<td>1,077</td>
<td>47%</td>
</tr>
<tr>
<td>Pharma PPE</td>
<td>234 M</td>
<td>322</td>
<td>37%</td>
</tr>
<tr>
<td>Ambulances, smart hospitals, goods &amp; services</td>
<td>181 M</td>
<td>243</td>
<td>34%</td>
</tr>
<tr>
<td>Total</td>
<td>1,150 M</td>
<td>1,642</td>
<td>43%</td>
</tr>
</tbody>
</table>


In the biennium 2020–2021 of the COVID–19 pandemic, PAHO procured health products for its Member States for a total of 2,792 million USD (Table 2). The increase in procurement value between 2020 and 2021 was +43%.

PAHO contributed to equitable access by providing quality-assured vaccines, medicines, and health supplies through its well established Strategic Fund and through a Revolving Fund. PAHO also joined the WHO ACT–Accelerator. PAHO does have Country Offices in most countries, so it received many new technical assistance requests on aspects related to the procurement processes of its Member States (regarding qualification of its suppliers, purchasing options, product–quality assurance, and funding, among others). These required an accelerated learning process for both local authorities and PAHO officers.

Local knowledge allowed PAHO to swiftly adapt its approach by looking for the most adequate supplies for countries according to their needs. This characteristic was important to avoid problems related to issues such as voltage use in the purchase of ventilators by organizing supplies by their voltage.

PAHO deployed National Coordination Strategies with the purpose of enhancing regional production capabilities. For instance, PAHO led an initiative to exchange local experiences for the “Development and Production of Ventilators in the Context of COVID–19.” It summed up activities and boosted 20 initiatives related to innovative ventilator production in countries such as Argentina, Brazil, Colombia, Costa Rica, Mexico, Trinidad and Tobago, and Uruguay and added some factories in the USA and Spain. The developers were integrated in an attempt to share information and boost local production. On this initiative, there was cooperation between incumbents, such as planning of stages of development from design to testing and production, a signature of maturity shown under exceptional circumstances by private sector participants.
The PAHO Revolving Fund (14) is the designated procurement agency for COVAX in the Americas. The COVAX facility procurement mechanism purchased vaccines from a portfolio of producers on behalf of its member countries. PAHO coordinated deliveries with other COVAX partners and supported international logistics to ensure the safety and timely delivery of vaccines, has made supply agreements, and provided 93 million vaccines to 19 countries in Latin America. COVAX has also provided an innovative financing instrument to support the participation of low- and middle-income countries, including Bolivia, El Salvador, Haiti, Honduras, and Nicaragua, all financed through the Covax facility.

PAHO’s Revolving Fund (for vaccines) and Strategic Fund (for medicines and health supplies) were primary sources of health products. Thus, PAHO’s participation in acquiring essential health products was very significant in most Latin American countries, mainly in LMICs, that did not have access to direct purchases. Its involvement encompassed funding, coordinating, purchasing, and delivery in some cases.

These new skills learned in the field have led organizations like PAHO to take on new risks, innovate, and improve technical collaboration with Member States, with a hands-on, evidence-based approach that will be valuable for future crises.

Lessons and discussion

- Greater incentives should be placed on preparedness and long-term planning in low- and middle-income countries.
- Government intervention in crisis events should help harmonize supply chains for needed items, allowing reduction of bureaucratic requirements regarding purchases, imports, and authorization of products, as well as providing leadership in decision making in order to increase coordination between supply and demand.
- Commitment from highest political levels with population health objectives and clear frames of implementation is of utmost importance during health crises.
- Information sharing increases the speed of reaction. Digital advancement and collaboration between countries and regulatory agencies should be reinforced.
- Alliances and international and public-private cooperation provide collaborative solutions that greatly improve problem resolution in global catastrophes.
- The role of multilateral organizations is essential and should be enhanced in crisis situations, particularly in supporting medium and low-income countries with less resources.
3. Regulatory preparedness

Regulatory systems for medicines and other health technologies for emergency response play an essential role in health systems, including public health emergencies. Yet in some countries, the regulatory system for medicines is not equipped to respond during public health emergencies and/or is not well integrated into the national emergency response. The ongoing COVID–19 pandemic has provided an opening to critically analyze the need and the value of these systems in emergencies, assess their strengths, and identify opportunities for improvement in the Americas.

National regulatory authorities (NRAs) ensure that robust mechanisms are in place to adapt to a rapidly changing environment as new products become available for treatment, diagnostics, and other COVID–19–related uses (15).

In April 2020, the Pan American Health Organization formed a network of NRA focal points to identify regulatory obstacles related to the COVID–19 pandemic and provide guidance on how these might be overcome, as well as promoting the timely exchange of information among NRAs in the Region. The characterization and analysis of the existing regulatory mechanisms for the COVID–19 response in the Region were supported by this network in November 2020. As shown in Figure 3, 62% of NRAs would use the Emergency Use Authorization (EUA) as a regulatory strategy to authorize products required to respond to the emergency; nonetheless, EUA did not always imply an accelerated authorization procedure and, moreover, there was heterogeneity between the requirements defined for each country in the use of this alternative.

![Figure 4: Regulatory mechanisms for COVID–19 vaccine approval used by the national regulatory authorities of 21 countries of the Region of the Americas, November 2020](image)


In 2021, lessons learned on regulatory emergency response to the COVID–19 pandemic in selected Member States were published. These data show that Latin American National Regulatory Authorities of Regional Reference (NRAr) implemented emergency regulatory measures across a variety of domains and took many actions very early in the pandemic (see Figure 4) (16). The countries participating were Argentina, Brazil, Chile, Colombia, Cuba, and Mexico.
3.1. Essential health products

The key question to address on this point was if any essential health products to manage the COVID-19 pandemic have been identified.

- All Latin American NRAs have made the list of the MHT needed for COVID-19 response available on their websites. This served as the prioritization processes required to make those products available at the country level.
- However, smaller states with less strengthened regulatory systems that did not have an essential list of products benefited from PAHO’s lists (17).
- Countries such as Costa Rica implemented a series of workshops to strengthen human resources capacities in primary healthcare systems on the minimum standards required for PPE, including but not limited to: medical masks for healthcare workers and patients and particulate respirators, according to the different reference international certified bodies (e.g.: minimum NIOSH approved “N95,” EN 149 minimum “FFP2,” GB 2626, and minimum “KN95,” among others) (17, 18).

Notes: * P-T-H: Pharmacovigilance, technovigilance, and hemovigilance. The figure shows the areas in which regulatory actions are categorized. Each bar represents a month and despite the fact that regulatory actions are usually sustained over time, this helps to visualize where efforts are concentrated. Most of the regulatory actions focus on the relaxation of regulatory requirements. Areas such as market surveillance and control are those that have had less prominence. It can also be observed that most of the regulatory actions were taken in March and that in July there is an increase in the measures related to surveillance.

Source: Analysis performed using the regulatory actions shared by NRAs with PAHO through a common repository established during the emergency in the Regional Platform on Access and Innovation for Health Technologies (PRAIS).

During the COVID–19 pandemic NRAs were involved on three key critical areas: a) identification of essential health products to manage the COVID–19 pandemic, b) flexibilization of regulatory requirements, and c) market control to avoid the risk of shortages and promote rational use. When comparing actions taken by other countries also included in this study the following similarities have been found, as described in the upcoming sub–sections.

* Costa Rica, Dominican Republic, Guatemala, Haiti, Paraguay, and Suriname
3.2. Flexibilities in regulatory requirements

During this assessment, flexibilities implemented in regulatory requirements were explored, as part of the regulatory response.

- Flexibility regarding physical documentation requirements was observed among Member States. Virtual communication channels to expedite submissions became paramount as part of the emergency response. In some cases, this allowed countries to reduce the length of the procedures to import COVID-19–related products (16).
- NRAs have extended renewals and validity of authorizations, certificates, and licenses for products and/or manufacturers, importers, and distributors. Most exemptions and abbreviated procedures were related to PPE and diagnostic products. Measures included exemptions in compliance with labeling and insertion of packages, or with the verification of documents, as well as acceptance of incomplete applications (e.g., with pending laboratory analysis documents) (18).
- As the COVID-19 pandemic began to unfold, the Caribbean Regulatory System (CRS) used new guidance on how to use reliance to create a reliance–based review mechanism for the expedited verification of medical products for emergency use against this new virus. The CRS also signed confidentiality agreements with WHO to access information for granting authorizations of imported MHT when those are procured by the 11 COVID–19 vaccines. After reviewing, and considering WHO’s own assessments, the CRS shared its findings with its Member States and issued a certificate of recommendation for each vaccine. These certificates, and their accompanying reports, are expected to facilitate decisions on emergency use authorization or import permits, and help countries verify that sourced vaccines are essentially “the same” (in terms of components, packaging, and manufacturers) as those listed by WHO. Several countries, including the Bahamas, Dominica, Grenada, Guyana, St. Lucia, and St. Vincent and the Grenadines, have already used CRS recommendations to issue an import authorization and are now receiving vital vaccine supplies (19).
- In addition, prior to COVID–19 vaccine deployment several countries introduced/updated local regulations to expedite the approval of COVID–19 vaccines also using regulatory reliance principles recommended (Argentina, Barbados, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, Guatemala, Haiti, Mexico, Paraguay, and Suriname (20–33).
- The access to non–public information on the 11 WHO EUL COVID–19 vaccines was granted to 25 Member States under confidentiality agreements. This information was a key component of the local decision–making processes to facilitate access to the available vaccines. All countries included in this analysis have exceptional mechanisms for granting authorizations of imported MHT when those are procured through PAHO Revolving Funds, so requirements for importing those goods are minimal (34).

3.3. Regulatory measures enforcement

As part of the last dimension assessed, it was analyzed whether regulatory measures were enforced to avoid risks of shortages and promote rational use of essential health products.

- In some countries companies were urged to report any identified risk of shortage from the listed essential products.
- In manufacturing countries, in some cases, companies were mandated to require authorizations from NRAs prior to the export of prioritized essential products.
- Several authorities also modified the sales conditions of selected medicines in pharmacies, like hydroxychloroquine and antibiotics such as azithromycin, requiring medical prescriptions to dispense these products in order to avoid stockouts that could affect patients in need of the treatment for other medical conditions.
- Vigilance and control activities required a lot of effort from NRAs, and in some cases, there was a call to suppliers to provide pertinent information regarding the traceability of products, and to report any adverse events according to the country’s pharmacovigilance, technovigilance, and reagents surveillance programs to overcome challenges faced in regulatory oversight.
- Important actions related to pharmacovigilance and market control include the publication of guidelines for adverse event reporting in relation to plasma transfusions; the development of guidelines for the monitoring of adverse events in patients with COVID–19 under treatment with chloroquine or hydroxychloroquine; and the provision of safety information to the population on tocilizumab and chlorine dioxide (35–37).
- Additional actions related to clinical trial oversight, licensing, and regulatory inspections are available at (16).
Best Practices and Efficiencies

The ongoing experience with COVID-19 highlights a number of potential best practices and efficiency for regulatory action during emergencies, even though COVID-19 is unique in terms of its pervasiveness and duration of threat. These best practices and efficiencies appear to include the following:

- **Flexibility in regulations and processes.** Numerous NRAs’ actions point to the need to be flexible in emergencies, including having up-to-date policies and procedures, such as emergency use authorization and extension of certifications and periods of validity, among others.

- **Virtual strategies.** NRAs have taken advantage of modern modes of communication such as using virtual documentation and the conduct of work in virtual formats.

- **Faster timelines.** Faster timelines for regulatory processes are important, and examples include an expedited review of clinical trial applications.

- **Prioritized resources for emergency efforts.** Latin American NRAs have focused their efforts on 24/7 operations, including prioritization of regulation of emergency-related products.

- **Learning and information sharing.** Agencies continue to learn much from what other agencies are doing, including through information exchange.

- **Communications.** Enhanced communication with stakeholders is an essential aspect of emergency response. This includes communication with the public to provide accurate and up-to-date information, with the industry to understand new developments or potential shortages, with academia to identify much-needed expertise, and with local or international government representatives to coordinate emergency actions.

- **Reduction of duplication of efforts.** The increased use of reliance to respond to the ongoing COVID-19 pandemic is worth carefully considering in order to increase regulatory efficiency, such as in GMP inspections.
4. Supply chain management

Global value chains were one of the channels for transmitting the effects of COVID-19 to global trade. The logistics of trade was an essential element of the COVID-19 response effort. It refers to all the interconnected operations and activities needed to distribute goods in global commodity chains (Figure 6). These processes, analyzed in this chapter, were affected during the COVID-19 pandemic: lockdowns and travel restrictions at the outset of the COVID-19 pandemic disrupted activity in every sector of the economy, including the healthcare sector.

Figure 6: Logistics processes

Global logistic chains were in tension, particularly in the healthcare sector, where an excess of demand was observed globally on certain MHT. As stated by WHO’s Regional Office for Europe: "The pandemic has shown that many countries relied on a limited production of basic essential protection equipment and fragile supply chains, and faced shortages of medicines, medical equipment, health commodities and trained staff.”

The scale of the problem required, among others:

• the collaboration between public and private sectors including international organizations to effectively deliver MHT to those most in need.

• the availability of trained-qualified personnel in the logistics processes as well as in the use of health technologies. Installing equipment, such as ventilators or oxygen concentrators, running PCR-tests, applying vaccines, among other skills were important aspects of crisis response. Sharing that knowledge during an emergency is essential and it usually consists of several levels: trainers must be trained as well.

The challenges experienced and lessons learned in each of the logistics processes (Figure 6) involved in the MHT supply chain are presented below.

4.1. Shipping and customs

International shipping costs increased by 72% between the first quarter of 2020 and the third quarter of 2021, due to international shipping disruptions, such as health containment policies due to COVID-19, which slowed down the processing of goods at major ports.

Table 3: WORLD AND LATIN AMERICA AND THE CARIBBEAN: CHANGE IN THE VOLUME OF GLOBAL TRADE IN GOODS, DECEMBER 2019–MAY 2020

<table>
<thead>
<tr>
<th></th>
<th>Exports</th>
<th>Imports</th>
</tr>
</thead>
<tbody>
<tr>
<td>World</td>
<td>-18.3%</td>
<td>-15.8%</td>
</tr>
<tr>
<td>Latin America and the Caribbean</td>
<td>-26.1%</td>
<td>-27.4%</td>
</tr>
</tbody>
</table>

Source: (38)

Latin America and the Caribbean (LAC) was the most affected developing region with regards to trade and supply chain at the outbreak of the COVID-19 pandemic (38). As per Table 3, during the first months of the pandemic the contraction of international trade (exports and imports) had a greater impact in Latin America and the Caribbean. While between December 2019 and May 2020 world imports contracted by 15.8%, LAC imports fell by 27.4%, affecting the ability of countries in the region to purchase critical supplies. In the same period, the fall in exports had a negative impact on economic growth in LAC, registering a decrease almost 8% greater than the reduction in exports at the global level.
As for maritime trade, the impact in the region was important, falling by 20.9% by May of 2020, far exceeding the global slowdown (-11.4%), as shown in Table 4. PAHO’s coordinated response efforts with 35 countries in the Americas were a driving force for shipping healthcare supplies and PPE during times that trade was affected.

Table 4: Year-on-year change in international maritime trade in Latin America and the Caribbean, January–May 2020

<table>
<thead>
<tr>
<th></th>
<th>Jan</th>
<th>Feb</th>
<th>March</th>
<th>April</th>
<th>May</th>
</tr>
</thead>
<tbody>
<tr>
<td>World</td>
<td>1.8%</td>
<td>-6.2%</td>
<td>-3.9%</td>
<td>-15.9%</td>
<td>-11.4%</td>
</tr>
<tr>
<td>Latin America &amp; Caribbean</td>
<td>3.1%</td>
<td>2.9%</td>
<td>2.5%</td>
<td>-16.6%</td>
<td>-20.9%</td>
</tr>
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One of the major constraints was time. For instance, buying a ventilator usually takes up to four months between the purchase and the installation in a local facility. During the COVID-19 emergency, timeframes had to be optimized. Some Latin American governments resorted to their armed forces air fleets to transport essential health products and, when they existed, to special flights of public commercial airlines.

International organizations such as the UN, WHO, and PAHO intervened, providing shipping of essential healthcare products, such as PPE. As per Figure 7, 227 shipments of PPEs have been dispatched to PAHO Member States since the start of the pandemic.

A major constraint at the outset of the COVID-19 pandemic was border closure, which generated important delays in the supply chain processes that impact on availability and prices of MHT.

The World Trade Organization (WTO) delivered a trade policy instrument, the Trade Facilitation Agreement (TFA) supporting concepts such as an all digital clearance process and efficient risk management, by implementing risk-based custom processes that balance compliance needs with trade facilitation. Clearing processes for essential products could be managed remotely and digitally, protecting the health of customs officers and shipping personnel (40).

International coordination through multilateral organizations was important in reducing the negative impact of shipping constraints. From the onset of the pandemic Member States required PAHO support to deliver COVID-19 PCR tests, sample collection kits, rapid antigen diagnostic tests, genomic surveillance tests, and more than 200 shipments containing several types of PPE.

4.2. Storage

Storage facilities are central to logistics strategy, with the purpose of stocking, safeguarding, and delivering efficiently to end user facilities. The existence of logistical nodes for storage and distribution (hubs), vectors (transport lines), and mediums (transportation modes) is not well developed in large portions of Latin American countries, limiting the response possibilities of individual countries during the pandemic outbreak (41).


Source: (39)

The implementation of custom policies such as the TFA Agreement is key to improve the relation between the need for compliance and trade facilitation. Digitalization and risk management are important elements of the modern supply chain.
In some countries, such as Colombia and Haiti, large, centralized storage facilities were used. Haiti’s central storage is co-administered by PAHO and has direct customs clearance.

At a subnational level, barriers were identified in storage and last mile delivery. In some countries getting from the central storage facility to certain regions with challenging geographic terrain limited vehicular transportation to some remote areas. Developing smaller sub-regional storage hubs should be further analyzed on a case-by-case basis to determine how equitable access in remote regions could be improved.

It was critical also that vaccine national deployment plans were in place to make sure that when the vaccines became available, countries did have the capacity to store them according to the cold chain conditions required. Although the majority of the vaccines used in the national immunization programs were stored under refrigerated conditions (2°C to 8°C), some of the newly available developed COVID-19 vaccines required ultra cold storage conditions (-90°C to -70°C). The emergency use authorizations of COVID-19 vaccines were issued based on rolling data submission processes, and thus changes in product characteristics required expeditious processes to review and update immunization guidelines to avoid mistakes during storage and distribution, but also on anticipating the capacity required for proper storage (e.g., some vaccines that at the beginning required diluent prior to their use no longer require it because of formulation improvements).

### 4.3. Last mile delivery

Last mile logistics is the final step in a delivery process. It begins at the distribution center and ends when the delivery is successfully completed. Most often, last mile logistics involves the use of parcel or small package carriers to deliver products to consumers. Last mile logistics allows shippers to get more products to consumers faster and at lower cost (42).
Supply chain management

4. Supply chain management

only related to limited storage capacities, but also the logistics involved in handling procedures of the different vaccines involved, with different product characteristics (presentations, storage conditions, dosage, short shelf life, and target groups, among others), the infodemics, and misinformation which caused controversy and affected communities’ acceptance of vaccination. Providing simple guidance on how to make use of oversupply of COVID-19 vaccine doses to close gaps in vaccination coverage became a priority for PAHO/WHO and Member States as part of the supply chain management (44).

Once necessary products arrived and were stored, last mile distribution through the territories and delivery to local storage facilities, hospitals, and pharmacies was not an easy task during the pandemic. In the case of government-distributed products, last mile complications regarded logistics, transport, storage, and allocation. In the case of market products, pricing and market regulation must be added to the list.

In some countries, for instance, at the beginning, there were enzyme shortages, which led to difficulties to perform PCR tests. During the second wave, between April and May of 2021, there were oxygen and anesthetics shortages in hospitals. In other countries, there were some PPE shortages during the first months of the COVID-19 pandemic.

The case of scarce goods that were sold to the population and were not exclusively supplies, such as PPE, gel alcohol, and especially masks, was initially complex, leading to logistic “infodemias”: people did not know what to buy and ran to pharmacies or supermarkets in despair. In some countries, some masks had to be removed from the market to prioritize their supply in hospitals.

Scarcity of essential products was not evenly distributed. In times of uncertainty, some countries gathered much more than what they needed, while some could not have access to basic goods. This led to problems in every supply chain and prices were multiplied by 4 or 5 times.

To maintain supply and prices, some countries like Uruguay published a list of the minimum, maximum, and average price of sanitizers; others, such as Chile, invited suppliers to provide information on availability of stocks, for example of N95 masks, hand sanitizers, disposable gowns, thermometers, and other materials; and other countries, such as Argentina and Paraguay, directly used control price mechanisms like maximum prices (43).

Since the last quarter of 2021 countries in the Region have been receiving increasing amounts of COVID-19 vaccines. This required them to implement strategies to ensure timely immunization practices and avoid expiration of vaccine batches and consequent discarding. Countries faced obstacles, not

Managing a mass vaccination campaign is a huge logistical challenge, with decision responsibilities and implementation tasks related to issues such as vaccination locations, facility layout, the order in which the population is vaccinated, and staffing, refrigeration, and storage, etc.

Most countries handled the second COVID-19 wave, in 2021, much better than the first one, in 2020, even though the speed of spread was much higher during the former. In most cases, vaccine logistics did work better, although supply constraints were frequent. This performance improvement is multicausal:

- Logistics procedures, frameworks, and suppliers were in place with a year of emergency experience.
- Supply chains did not shut down completely again.
- Demand was better calculated, and constituents acted with increased rationality and patience.
- Frontline health workers were the first to be vaccinated, as well as older fragile populations, lowering severity and death toll despite increased contagiousness.
- The Health Ministries, procurement agents, NRAs, and logistics operators gained expertise and resilience in mastering complex situations.

Vaccines distribution - an example of built capabilities.

“Defining a public policy for vaccination against COVID-19 is one thing, ensuring its proper execution is a far more complicated issue. Faced with the complexity of delivering millions of doses, only national and transversal coordination will ensure a smooth vaccination campaign. The risk of queues, shortages of doses, unused stocks ordered, trafficking in vaccines by ill-intentioned individuals... Never has the proper execution of a public policy been so crucial” (42).

4. Supply chain management
Internet of Things (IOT) in logistics

IOT are all those electronic devices with the ability to connect to the Internet. COVID-19 has been a catalyst for the application of the Internet of Things (IOT) in the transportation and logistics sector. IOT improves efficiency in:

- the last mile delivery service, optimizing delivery, traceability, and distribution processes. Some pharmaceutical companies provided picking size storage with an internal chip that measured temperature, signaling a centralized computer when temperatures were outside defined parameters, so that those lots could be separated and disposed of to prevent them from reaching the population.
- fleet management, ready to provide emergency solutions to unexpected situations. Most small truck units in charge of last mile delivery had IOT devices installed that could track deliveries and trace lots assigned, to maximize control and efficiency in delivery.
- warehousing, stock controls, purchasing optimization, and picking and distribution processes. In addition, they allow greater worker safety and fewer workplace accidents. For example, software connected the parked lots with warehouses in a logistics operator in Argentina, in charge of vaccine warehousing and delivery of low temperature vaccines, to ensure first expiry–first out processes for vaccines and other medical products.
- Establishment of an updated electronic inventory management system for vaccines and supplies.
- Cobots: Arm robots are being installed to perform picking operations efficiently, in collaboration with human beings to optimize the picking process. These are part of IOT 4.0 technologies.

One of the major constraints that supply chain operators face in the deployment of IOT technology is finding workers that combine logistics savvy with connectivity skills.

4.4. Recalls

Another issue during the COVID–19 pandemic was health products withdrawal. It was cumbersome to take a health product out of the market when it was found that it was not suitable, necessary, or safe. In some countries, products that were recommended by some subnational health authorities were not so by others, which led to confusion. That was, for instance, the case of hydroxychloroquine and ivermectin.

In the Caribbean, a major concern was the proliferation of substandard and falsified health products. There were people and stores that offered products and even alleged vaccines without health authorization. In Trinidad and Tobago a large shipment of hand sanitizers had to be withdrawn because methanol was found in it. Mexico, Brazil, Peru, and Costa Rica also faced the problem, registering cases of falsified and substandard medicines, tests, and even vaccines (16).

Recommendations (16)

- Strengthen coordination to facilitate active support and participation of all stakeholders in pharmacovigilance and post–marketing surveillance activities.
- Strengthen efforts to integrate pharmacovigilance and post–marketing surveillance information into evaluation and, where appropriate, regulatory action.
- Establish national tracing systems that contribute to international drug surveillance and safety systems, and support drug safety measures related to reporting on substandard and falsified products.
- Monitor markets and promote efficiency by using decisions of other regulatory authorities.

Lessons and discussion

- Countries need to build infrastructure and connectivity to be able to fulfill the delivery of health products efficiently, analyzing capabilities in all stages encompassing international freight, customs, warehousing, to local last mile delivery.
- Logistics investments should consider new available technologies like IOT that bring renewed individualized tracking, efficiency, and control in the logistics operation.
- Latin America and the Caribbean could explore strategic integration in logistics chains with hubs and vector routes in a collaborative approach.
- Border closures can be disruptive to supply chains and should be questioned for basic medicines and related products distribution in line with the “One Health” program fostered by WHO.
- Multilateral organizations should include technical support in their negotiation with suppliers to ensure devices get installed properly at the needed times.
- One of the most valuable resources that multilateral organizations can provide to member countries is training. Building capabilities in areas such as planning, strategy, logistics, purchasing, and regulation allows countries to confront situations such as establishing massive vaccination programs successfully.
Discussion: future response preparedness

• COVID-19 impacted health systems globally and regionally. The effectiveness of the supply chain was decisive in responding to the care needs of the population.
• Preparedness is key: it is a good practice to develop disaster preparedness plans in coordination with the appropriate international organizations.
• Multilateral organizations play an important role in encouraging preparedness and coordination, and increasingly a hands-on role in financing, training, and delivering essential products, particularly to low income and resources countries.
• More accurate epidemiological data and predictions are needed to: i) improve estimation of key epidemiological parameters; ii) design and implement systematic data collection; iii) create early warnings.
• Building alliances between the public, private, and academic sectors allows finding collaborative solutions, aligning incentives, and directing resources according to the defined priority agenda.
• Coordinated purchasing: coordinated purchasing processes avoid multiple tenders, avoiding price distortions due to increases in demand and centralizing the channels for supply.
• Strategic integration into logistics chains through hubs and vector routes should be explored, so as to allow for rapid availability and economies of scale.
• Long-term investment is needed: countries need to build infrastructure and generate connectivity to have more efficient supply systems. It is essential to improve the transport and communication infrastructure, including connectivity in Latin America. It was noted that lack of them could reduce the effectiveness of the countries’ response to crises and unforeseen events. Logistics investments must evaluate the incorporation of new technologies such as IOT that provide individualized monitoring, efficiency, and control in the logistics operation.
• Training investment is needed: when managing purchases, it is relevant to assess whether technical support from suppliers will be required to train those who will use the products or monitor their correct use (e.g., medical devices).
• NRAs should proactively develop regulations, policies, and procedures that facilitate strong regulatory emergency response. NRAs should avoid duplication of efforts in the regulatory process and improve decision making based on risk-benefit criteria. When establishing a regulatory framework for emergency, the general universal principles that should guide and inform NRAs’ decisions should also be considered:
  - transparency,
  - decision making consistent with national legislation,
  - and the establishment of procedures based on potential risks.
• NRAs should focus their efforts on activities they must perform regardless of the procurement channel used to respond to the emergency: post-introduction surveillance and monitoring of medical products, continuous risk-benefit assessments on the use of medical products introduced in emergency situations, and timely detection of possible substandard or falsified medical products.
• Countries should establish communication and coordination mechanisms between the different actors involved in the procurement process: medical products, including vaccines, are usually imported with the supervision and participation of various actors such as NRAs, customs authorities, and port control authorities, among others. All participating agencies should coordinate their actions in order to improve and expedite clearance and importation.
• Regional approaches can be the basis for strengthening local production capacities of MHT. This approach would contribute to a geographical diversification of the production of strategic MHT towards neighboring countries for better preparedness and response to future emergencies while providing sustainability by allowing other regional health needs to be met between emergency periods.
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The general purpose of this study is to provide insights to decision-makers and health practitioners on aspects related to the supply chain for medicines and other health technologies (MHT) for emergency response. The main goal is to capitalize on lessons learnt during the COVID-19 pandemic so that countries are better prepared and count on adequate management tools for future pandemics, following an emergency preparedness framework. The study builds on information gathered from official reports and publications, from consultations to key local personnel involved in the supply chain for MHT for emergency response, healthcare staff and practitioners. Additional sources of information were interviews performed to regional specialists from PAHO headquarters, as well as information published by international organizations.