Report of the 10th Conference of the Pan American Network for Drug Regulatory Harmonization (PANDRH)

The Regulatory Systems in the Health Agenda Post COVID-19

PAHO
Pan American Health Organization
World Health Organization
REGIONAL OFFICE FOR THE Americas

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Extraordinary online session
6, 8, and 10 December 2021
Washington, D.C., 2023

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Contents

Acknowledgments

The Pan American Health Organization / World Health Organization (PAHO/WHO), acting as the Pan American Network for Drug Regulatory Harmonization (PANDRH) Secretariat, is grateful to all those who made this Conference possible.

Particular thanks are due to all chairs, moderators, panelists, keynote speakers, and rapporteurs for their availability, flexibility, and constructive spirit, which allowed the Conference's goals to be achieved and promoted the exchange of challenges and good practices in the management of the pandemic.

Thanks also go to all the attendees for their online participation in the various channels made available for this Conference. Their involvement and interest in the discussions of the Conference are key to continue strengthening the regulatory functions and systems of the countries of the Americas.

Special thanks and recognition are also due to all the national regulatory authorities of the Region of the Americas for their critical work and contributions to the COVID-19 response, and for actively participating in this year's Conference, amid the pandemic.

The PANDRH Secretariat remains committed to supporting the processes of pharmaceutical regulatory harmonization in the Americas.

Abbreviations and acronyms

ALIFAR	Latin American Association of Pharmaceutical Industries
ANMAT	National Administration of Drugs, Foods, and Medical Devices of Argentina
ANVISA	Brazilian Health Regulatory Agency
ARSA	Sanitary Regulation Agency of Honduras
CARICOM	Caribbean Community
CARPHA	Caribbean Public Health Agency
CECMED	Center for State Control of Drugs and Medical Devices of Cuba
COFEPRIS	Federal Commission for Protection against Health Risks of Mexico
CRS	Caribbean Regulatory System
EMA	European Medicines Agency
EUA	emergency use authorization
EUL	emergency use listing
FDA	United States Food and Drug Administration
FIFARMA	Latin American Federation of the Pharmaceutical Industry
GBT	Global Benchmarking Tool
INVIMA	National Food and Drug Surveillance Institute of Colombia
ISP	Public Health Institute of Chile
NRA	national regulatory authority
PAHO	Pan American Health Organization
PANDRH	Pan American Network for Drug Regulatory Harmonization
UMC	Uppsala Monitoring Centre
USP	United States Pharmacopeia
WHO	World Health Organization

Introduction

The 10th edition of the Pan American Network for Drug Regulatory Harmonization (PANDRH) Conference was organized as a virtual summit, for the very first time, due to the ongoing COVID-19 pandemic. Participants included representatives from national regulatory authorities (NRAs) of the Americas, the World Health Organization (WHO), the Pan American Health Organization (PAHO), the pharmaceutical industry, and nongovernmental organizations, among others.

The Conference took place on the 6, 8, and 10 December 2021 under the theme The Regulatory Systems in the Health Agenda Post COVID-19. An average of 248 attendees and 205 YouTube viewers came together during these three days to reflect on and analyze the role of regulatory systems in the COVID-19 response and their importance in the postpandemic health system agenda. The Conference had three plenary sessions:

Plenary 1: Strengthening, integration and pending agenda: the evolution of regulatory systems 2010–2020

Plenary 2: The contribution of the regulatory systems in the Region of the Americas to the response to the COVID-19 pandemic

Plenary 3: The regulatory systems in the post COVID-19 agenda

The Conference materials, including the session recordings, are available online (*1*). The agenda is included in Annex 1 of this report.

In the following pages, a summary of the discussions and directions from the Conference is depicted. This report should not be considered as a full transcript of the Conference.

Conference inauguration and report from the Secretariat

The Conference was inaugurated by PAHO's Director, Dr. Carissa Etienne, who welcomed participants to the meeting and offered opening remarks. In her intervention, Dr. Etienne highlighted that never in the history of public health in the Americas had the collective actions of NRAs and industry been so important. She recognized the pivotal role of NRAs in any endeavor to increase access to lifesaving drugs, and called on Member States to adopt a new strategy and renewed commitment to strengthen national regulatory systems.

After the opening remarks, Dr. Analía Porrás, PAHO Unit Chief for Medicines and Other Health Technologies, presented the PANDRH Secretariat's Report. The Secretariat recognized the regulatory advances in the Region, especially those related to the adoption of the concept notes on regulation of advanced therapies (*2*), regulatory reliance principles (*3*), and regulatory system models for small States (*4*) have changed the regulatory paradigm in search of regulatory efficiencies, with relevant impact at the regional and global levels.

The Secretariat also presented some of the key findings of the report Lessons Learned from National Regulatory Authorities of Regional Reference published in 2021 (*5*). Among the highlighted results, it was mentioned that the most developed regulatory systems in the Region are characterized by NRAs with a prominent position within the health system hierarchy, suggesting that authorities with more administrative and technical independence are better equipped to fulfill regulatory functions. It was also underscored that, despite the fact that the pharmaceutical market of the Americas has grown in volume and value, annual budgets for NRAs have remained static. This highlights an important challenge for agencies to respond to an increased volume of work with stagnant funding.

The cases of the Caribbean Regulatory System (CRS) and the Central American Mechanism were also mentioned as an innovative subregional approach to regulation that pools resources and markets together, with a single set of standards. A call was made for increased support and information-sharing from other regulatory authorities and from the pharmaceutical industry to subregional regulatory systems.

The overall Region's regulatory preparedness for emergencies and response to the COVID-19 pandemic were also highlighted in the Secretariat's report. The publication of regulatory documents and creation of a pharmacovigilance dashboard to track vaccine safety evaluation criteria were underscored, as was the establishment, in April 2020, of a network of NRA focal points to detect and overcome regulatory obstacles related to the pandemic, and to promote the timely exchange of information between the NRAs in the Region. The adoption of emergency regulatory measures, and the use of decisions of other jurisdictions for the introduction of essential products, allowed Member States to avert regulatory delays in the entry of essential supplies for the response against COVID-19.

The WHO recommendations for the use of vaccines included in the emergency use listing, the facilitation of access by Member States to the evaluation reports of these vaccines, and the implementation of accelerated processes or exceptions for the authorization of the entry of products acquired through PAHO's revolving funds were noted as instrumental for the efficiency of regulatory authorizations in the countries. It was also mentioned that an important group of regulators from national regulatory authorities of regional reference (NRAr) in the Americas supported WHO in the assessment of vaccines recommended for emergency use, which fostered their readiness to receive those products without barriers.

Despite many advances, it was recognized that there are opportunities for improvement, increasing efficiencies in limited-resources settings, using reliance and work-sharing approaches. NRAs are called to adjust their legal framework and regulatory practices to enable risk-based decisions. Moreover, strengthening the postmarket

surveillance system is central to monitor the products that are being authorized under emergency exceptions or flexibilities, enabling timely regulatory decisionmaking.

Finally, the Secretariat presented the list of confirmed members of the PANDRH Steering Committee per subregion with a mandate from 2022 to the next Conference (Table 1).

Table 1. PANDRH Steering Committee Members (2022– Next Conference)

Subregion	Main	Alternate
North America	Mexico	Canada
Central America + Cuba + Dominican Republic	Honduras	Guatemala
Caribbean	**	**
Andean Region	Ecuador	**
South Cone	Uruguay	Paraguay
Observer members		
CRS	CARPHA	N/A
NRAr	ANMAT	N/A
ALIFAR*	Ruben Abete	Miguel Maito
FIFARMA*	Rafael Diaz-Granados	Maria Fernanda Hurtado

* Founding members.
** Member not yet confirmed.

Plenary 1: Strengthening, integration, and pending agenda: the evolution of regulatory systems 2010–2020

The first plenary of the 10th PANDRH Conference offered a space to reflect on the evolution of regulatory systems in the Americas since the adoption of Resolution CD50.R9 Strengthening National Regulatory Authorities for Medicines and Biologicals in 2010 (*6*), and opportunities for their strengthening.

The session was chaired by Elvia Lau, Panama's Director of Pharmacy and Drugs, and it was moderated by James Fitzgerald, PAHO Director of Health Systems and Services. Members of the panel included:

- Heriberto García Escorza, Public Health Institute, Chile
- Joy St. John, Caribbean Regulatory System / Caribbean Public Health Agency
- Olga Casanueva, Center for State Control of Drugs, Equipment and Medical Devices, Cuba
- Amanda Jane Diniz, Health Canada
- Miguel Maito, Latin American Association of Pharmaceutical Industries
- Rafael Díaz-Granados, Latin American Federation of the Pharmaceutical Industry

Panelists highlighted that Resolution CD50.R9 had been a turning point that triggered regulatory system strengthening in the Region, allowed the adoption of regional approaches to regulation, and increased convergence with international guidelines and international cooperation schemes. It was also mentioned that in the past 10

years an increased regional dialogue and collaboration had been observed between regulators and with the regulated sector with the goal of benefiting patients and societies.

The use of a standard evaluation system and benchmarking tools was also one of the advances highlighted as one of the achievements of the past decade. More than 75% of the regulatory authorities of the Region were assessed, which helped identify strengths and opportunities for improvement, and it led to the designation of eight regulatory authorities of regional reference. This designation attested to the functionality and regulatory oversight and capacity of these eight NRAs that cover over 82% of the population of the Region.

The creation of subregional regulatory mechanisms was also mentioned. These systems, as well as an increased use of reliance, and the establishment of accelerated approval pathways and mutual recognition mechanisms are some of the key determinants companies take into consideration when establishing their commercial strategies and to bring innovation to markets.

The panelists also analyzed the challenges and opportunities that the COVID-19 pandemic has brought. It was mentioned that the pandemic had launched a new era of reliance, and that it had also allowed an increased collaboration and regulatory harmonization. For example, the Public Health Institute of Chile's (ISP) and the Brazilian Health Regulatory Agency (ANVISA) exchanged inspection reports of Sinovac manufacturing sites in China with other NRAs in the Region to enable their decisionmaking process on accepting this vaccine in their territories, avoiding the burden and costs of additional on-site inspections.

Despite the advances and gains of the last 10 years, challenges remain that should be addressed to bring the next decade of regulatory system strengthening in the Americas. Panelists mentioned that despite the increased use of reliance, building trust among regulators and their industry partners remains key to ensure that medicines and other health technologies products are timely accessible for the population. Establishing mutual agreements between NRAs of the Region to officially enable the exchange of nonpublic information, report-sharing, and mutual recognition was mentioned as part of the pending agenda.

The use of reliance beyond marketing authorization also remains a challenge. The creation of regional mechanisms for inspections, including report-sharing, and building manufacturing plants in all subregions of the Americas, including the Caribbean Community (CARICOM), are elements that would indubitably facilitate access to quality health technologies.

The pandemic also showcased the unprecedented shortage of medicines and personal protective equipment throughout the Americas, and the problem that health systems faced as a result. According to panelists, building manufacturing plants and favoring the purchase of essential medicines and other health technologies that are locally produced should be a priority.

The need to further advance regulation of medical devices was highlighted by several panelists, while the need for more collaborative approaches, transparency, reliance pathways, and work-sharing were particularly emphasized. A call for a broader engagement with other stakeholders in the health system was made so that innovations and access to health technologies can be brought from regulation to broader clinical practice.

Based on the interventions of the panelists, the session was wrapped up by Catherine Parker, representative of the Committee of the Report on Regulatory System Strengthening in the Americas. Lessons Learned from the National Regulatory Authorities of Regional Reference (*5*).

Plenary 2: The contribution of the regulatory systems in the Region of the Americas to the response to the COVID-19 pandemic

Acknowledging the importance and challenge of the COVID-19 pandemic, the objective of the second day of the Conference was to discuss how regulatory efficiencies were implemented during the pandemic, what strategies were used by NRAs to facilitate timely access to needed health products, and the lessons learned. The session was chaired by Maria Antonieta Gamarra, head of Paraguay's National Direction of Sanitary Surveillance, who welcomed participants and introduced the keynote speaker for the plenary, Elizabeth Hillebrenner, from the United States Food and Drug Administration (FDA).

In her intervention, Hillebrenner offered an overview of the emergency use authorization (EUA) pathway for medical devices used by the FDA and some of the innovations implemented to respond to the 38% increase in submissions during 2020. The creation of an umbrella EUA for multiple devices with similar characteristics and that meet certain criteria, as well as the development of EUA templates and a frequently asked questions section in the FDA's website, were some of the strategies adopted to create efficiencies. Hillebrenner's presentation concluded by highlighting two key lessons learned: (*1*) the value of regulatory flexibility so the NRA can adapt to changing circumstances and have a timely response that facilitates availability of critical devices; and (*2*) the power of engagement and working together with technology developers to bring over 1900 new devices for COVID-19 to the United States market to date.

After the keynote intervention, the chair introduced the panel moderator, Murray Lumpkin, from the Bill & Melinda Gates Foundation, and the seven panelists:

- Daniel Rodríguez, PAHO/WHO
- María Margarita Jaramillo, National Institute for Drug and Food Surveillance, Colombia
- Alejandro Svarch, Federal Commission for Protection against Sanitary Risks, Mexico
- Hiiti Sillo, WHO
- Hervé Le Louet and Pinelopi Lundquist, Uppsala Monitoring Center
- Ron Piervincenzi, United States Pharmacopeia

Lumpkin started the panel session by reminding attendees that having quality healthcare products is an indispensable component for having a quality healthcare system, and that regulatory systems play a key role in assuring this. During the pandemic, this critical role did not change, but it had to be performed in a world of extraordinary unknowns where timeliness became of the essence, and where political pressures to expedite access to new technologies were a common challenge faced by all regulators.

Panelists representing regulatory authorities recognized the increased political pressures during the pandemic and mentioned that having quality assurance systems and science-based decisionmaking processes was critical to guarantee that products approved were of high quality, safe, and effective. However, cognizant of the importance of establishing expedited processes, increasing efficiencies, introducing flexibilities, and responding to the changing context, regulators shared some of the strategies implemented. For example, the National Food and Drug Surveillance Institute of Colombia (INVIMA) established an EUA process, and it also created a list of essential health technologies to facilitate importation of products that did not have marketing authorization but did comply with predefined criteria. The Federal Commission for Protection against Health Risks of Mexico

(COFEPRIS) also mentioned as key to facing the pandemic the digitalization of regulatory procedures and the need to establish mechanisms for the exchange of regulatory information for decisionmaking.

The growing recognition of reliance as best regulatory practice of the twenty-first century and its increased use during the pandemic was also discussed. WHO shared that 15 days after the prequalification team had issued the first emergency use listing (EUL) of COVID-19 vaccines, 101 countries used a reliance base process to provide EUA. Furthermore, it is expected that reliance practices will be strengthened thanks to the use of the Global Benchmarking Tool to generate evidence of NRA's performance and to designate WHO-listed authorities.

Despite the benefits of using reliance and other expedited procedures for authorization and importation, NRAs were still responsible for balancing the risk of allowing the entry of needed medical products for which there was limited information and/or were sourced from unknown manufacturers and markets with less-mature regulatory oversight. Pharmacovigilance and surveillance systems became crucial in this context to monitor the safety and efficacy of these products, and to take regulatory actions if necessary.

To support these surveillance activities, the Uppsala Monitoring Centre (UMC) prepared and adapted its tools for reporting COVID-19 vaccine events, facilitated training, and published reports on the observed global patterns from the 2.7 million vaccine reports received to complement the work of regulatory systems. Regulatory authorities, like INVIMA, highlighted the importance of communication and working closely with service providers, such as immunization programs, and with everyone involved in the supply chain so that reports of events are received and that appropriate follow-up and regulatory action takes place.

The issue of substandard and falsified medical products during the pandemic was also addressed in the panel. The United States Pharmacopeia (USP) mentioned that the high demand for products and the constricted supply chain observed during the COVID-19 pandemic created an optimal environment for substandard and falsified medical products. Panelists highlighted the need to develop strategies for rapid detection and response, as well as promoting means for the end-user to have the tools that allow them to recognize and report any potential falsified products.

Another challenge discussed in the panel was the disruption of pharmaceutical supply chains. Scarcity of medical products, protectionist policies, and disruption of air traffic were some of the challenges faced by procurement agencies. The Region of the Americas was particularly vulnerable to these shocks. During the peak of the pandemic, only 4% of supplies were produced in the Region, showing great dependence on international markets. Building of local manufacturing capacities is imperative for better preparedness for the next emergency.

Michael Rosu-Myles, from Health Canada, did the panel wrap-up. In his intervention, Rosu-Myles highlighted the fact that COVID-19 posed a novel pressure on the regulatory systems, manufacturers, procurement agencies, and international organizations like PAHO/WHO. However, it also allowed for the adoption of regulatory efficiencies, enhancement of existing regulatory systems, and strengthening of global collaboration.

Plenary 3: The regulatory systems in the post COVID-19 agenda

The importance of the regulatory systems in the post-COVID19 health system agenda, as well as the good practices that should be extrapolated in the postpandemic stage were discussed in the last panel of the 10th PANDRH Conference. The keynote speaker of the session was PAHO's Assistant Director, Dr. Jarbas Barbosa da Silva Jr.

In his intervention, Dr. Barbosa noted that the COVID-19 pandemic offered the unique opportunity to critically analyze the value of the regulatory systems in the health and sustainability agenda post COVID-19. Regulatory issues will remain key as countries grapple with recovery and rebuilding efforts, including expanding manufacturing capacity. Dr. Barbosa finalized his presentation by highlighting that the future requires strategies for the strengthening of regulatory systems that contemplate convergence and harmonization under international standards, the advantages of collaborative approaches, and the use of reliance principles considering benefit-risk criteria, as well as the promotion of local supply chains that benefit access to quality products.

The plenary session followed the keynote presentation. This plenary was chaired by Marlan Cole from Guyana's Food and Drug Department, and moderated by Andreas Seiter, from the World Bank. Members of the panel included:

- Manuel Limeres, National Administration of Drugs, Foods and Medical Devices, Argentina
- Leonardo Sánchez, Sanitary Regulation Agency, Honduras
- Meiruze Freitas, National Health Surveillance Agency, Brazil
- Danielle Craig, Coalition for Innovations on Epidemic Preparedness
- Martin Harvey, European Medicines Agency

Panelists reflected on the lessons learned that should be applied to improve future emergency response. Increased and better communication was singled out by all panelists as something critical that can be enhanced in the next pandemic response. Developing capacities to communicate complex information on products' safety, efficacy, and quality to the general population is critical to increasing trust in regulators and the overall health system.

Stakeholder engagement was also heralded as a critical lesson of the current pandemic that should be strengthened in the future. Dialogues between regulators and developers should continue to be promoted to increase innovation and access to medical products. The inclusion of smaller developers in the discussions should be encouraged. Increased engagement and dialogue with other actors of the health sector, such as immunization programs, should also be strengthened to promote cohesive messages and integrated actions.

Though regulatory harmonization initiatives have been promoted in over the years, there is still a need to have a common understanding on how to interpret and implement standards. Global cooperation mechanisms, forums, and dialogues among regulatory agencies were identified as positive developments that can support the advancement of this common understanding and interpretation of international standards. This initiative was characterized as critical by the panelists because trust between regulators, which comes about through constant interaction over the years, is fundamental for regulatory efficiencies, such as reliance.

Looking five years into the future, panelists mentioned that they hoped to see in place appropriate mechanisms that would allow a faster regulatory response to emergencies to reduce economic impacts and save lives. They expect to see a common understanding that duplications should be avoided, and that not all regulatory authorities need to be a reference authority to fulfill their obligations to their citizens. Strengthening regulatory capacity does not always mean devising new rules but doing things right and making sure that end-users trust their regulators.

The plenary was wrapped up by Mary Lou Valdez, PAHO Deputy Director. Ms. Valdez thanked the panelists for their participation and reiterated the key role played by regulators during the pandemic for the delivery and access to key technologies, such as vaccines. She also stressed the importance of continued collaboration with all stakeholders to advance the regulatory agenda, increase transparency, promote regulatory coherence and reliance, and enhance information-sharing and communication.

Information session: New resolution "Policy to strengthen national regulatory systems for medicines and other health technologies" and consultation process

On the last day of the 10th PANDRH Conference, an information session took place on the draft resolution "Policy to strengthen national regulatory systems for medicines and other health technologies." The session was chaired by Ms. Laila Sofia Mouawad, ANVISA, and the presentation conducted by Dr. María Luz Pombo, PAHO/WHO.

Dr. Pombo started the session by reminding attendees that since the adoption of Resolution CD50.R9 in 2010 much progress had been achieved in terms of regulatory strengthening, harmonization, and convergence in the Americas. Yet, countries face new challenges in building efficient regulatory systems that are integrated into health systems and that can respond in an agile way to changing contexts and future emergencies. Furthermore, there is a growing interest in innovation and local manufacturing capacity-building in the Region.

Renewed regional mandates are necessary to respond to this new regional context, and to the establishment of a single global assessment tool, the Global Benchmarking Tool (GBT), in 2019. With the adoption of a new policy and resolution to strengthen regulatory systems, the NRAs of the Americas will have the opportunity to set a new direction for regulatory development in the Region, subject to public health interest, safeguarding the quality, safety, and efficacy of the products that enter their territories and contributing to sustainable production systems, and regional economic development.

The policy considers four main lines of work:

- Adopt sustainable State policies that strengthen the governance and stewardship of regulatory systems.
- Promote the strengthening of regulatory systems for consistent, transparent processes based on regulatory science.
- Strengthen regulatory harmonization and convergence.
- Adopt new evaluation systems based on the GBT and related mechanisms.

Dr. Pombo concluded her intervention inviting NRAs of the Region of the Americas to participate in the consultation process on this policy that would take place from February to March of 2022. Non-State Actors in official relations with PAHO were also invited to participate and send their comments when the document is officially published on the PAHO/WHO Governing Bodies' website.

Conclusions

Dr. Analía Porras, PAHO Unit Chief for Medicines and Other Health Technologies, offered concluding remarks of the 10th PANDRH Conference. Dr. Porras celebrated that the Conference had chairs from all the subregions of the Americas, and that other key partners were able to participate as panelists or moderators. Despite this new virtual format, the Conference achieved its goal of highlighting all the advances witnessed in the Region in the past 10 years and discussing the way forward.

Despite the successes, COVID-19 showed that there are still areas of opportunity for regulatory systems strengthening. For example, the need to strategically evaluate and increase regional manufacturing capacity of critical supplies, with appropriate regulatory oversight, is one of the pending challenges. A call was made for a renewed commitment with the assessment of regulatory capacities as a tool for continual improvement. Additionally, increased use and collaboration of subregional mechanisms, such as the CRS, should be promoted.

What the Region has achieved over the past decade in the regulatory arena has been due to cooperation, joint work, commitment to transparency principles, and great collaboration between agencies. Since its inception in 1998, the PANDRH network has fostered trust among the regulators of the Americas. The PANDRH Secretariat invited representatives of the industry to join efforts aimed at increasing collaboration and information-sharing.

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Annexes

Annex 1. Program of the 10th PANDRH Conference

10th Conference of the Pan American Network for Drug Regulatory Harmonization (PANDRH)

Extraordinary virtual session

6, 8, and 10 December 2021

The Regulatory Systems in the Health Agenda Post COVID-19

Day 1 Monday, 6 December	
9:00 – 9:30	**Preliminary sound and image tests on Zoom**
9:30 – 9:40	**Opening remarks** – Carissa F. Etienne, PAHO/WHO
9:40 – 10:20	Report of the PANDRH Secretariat (and Q&A): – Regional progress since the 9th PANDRH Conference – Objectives of the 10th PANDRH Conference (Analía Porrás, PAHO/WHO)
10:20 – 12:00	**PLENARY 1** **Strengthening, integration and pending agenda: the evolution of regulatory systems 2010–2020** **Chair:** Elvia Lau, Dirección Nacional de Farmacia y Drogas, Panama **Moderator and introduction:** James Fitzgerald, PAHO/WHO **Panel** • Heriberto García Escorza, Public Health Institute, Chile • Joy St. John, Caribbean Regulatory System/ Caribbean Public Health Agency • Olga Casanueva, Center for State Control of Drugs, Equipment and Medical Devices, Cuba • Amanda Jane Diniz, Health Canada • Miguel Maito, Latin American Association of the Pharmaceutical Industry • Rebecca Lumsden, Latin American Federation of the Pharmaceutical Industry Q&A and comments **Panel wrap-up:** Catherine Parker, representative of the Committee of the Report on Regulatory System Strengthening in the Americas. Lessons Learned from the National Regulatory Authorities of Regional Reference

Day 2 Wednesday, 8 December	
8:30 – 9:00	**Preliminary sound and image tests on Zoom**
9:00 – 11:00	**PLENARY 2** **The contribution of the regulatory systems in the Region of the Americas to the response to the COVID-19 pandemic** **Chair:** Maria Antonieta Gamarra, Dirección Nacional de Vigilancia Sanitaria, Paraguay **Keynote speaker:** Elizabeth Hillebrenner, United States Food and Drug Administration **Moderator and introduction:** Mac Lumpkin, Bill & Melinda Gates Foundation **Panel** • Daniel Rodríguez, PAHO/WHO • María Margarita Jaramillo, National Institute for Drug and Food Surveillance, Colombia • Alejandro Svarch, Federal Commission for Protection against Health Risks, Mexico • Hiiti Sillo, WHO • Hervé Le Louet and Pinelopi Lundquist, Uppsala Monitoring Center • Ron Piervincenzi, United States Pharmacopeia Q&A and comments **Panel wrap-up:** Michael Rosu-Myles, Health Canada
Day 3 Friday, 10 December	
8:30 – 9:00	**Preliminary sound and image tests on Zoom**
9:00 – 11:00	**PLENARY 3** **The Regulatory systems in the post COVID-19 agenda** **Chair:** Marlan Cole, Food and Drug Department, Guyana **Keynote speaker:** Jarbas Barbosa da Silva Jr., PAHO/WHO **Moderator and introduction:** Andreas Seiter, World Bank **Panel** • Manuel Limeres, National Administration of Drugs, Food and Medical Devices, Argentina • Leonardo Sánchez, Health Regulatory Agency, Honduras • Patricia Tagliari, National Health Surveillance Agency, Brazil • Danielle Craig, Coalition for Innovations on Epidemic Preparedness • Martin Harvey, European Medicines Agency Q&A and comments **Closing remarks:** Mary Lou Valdez, PAHO/WHO
11:00 – 11:30	**Information session: new resolution "Policy to strengthen national regulatory systems for medicines and other health technologies" and consultation process** **Chair:** Leonardo Dutra, National Health Surveillance Agency, Brazil **Presentation:** María Luz Pombo, PAHO/WHO **Moderation:** Analía Porrás, PAHO/WHO
11:30	Closing remarks: Analía Porrás, PAHO/WHO Photo

Annex 2. List of participants

A. Acronym glossary

Acronym	Organization	Country
AGEMED	Agencia Estatal de Medicamentos y Tecnologías en Salud *State Agency for Medicines and Health Technologies*	Bolivia (Plurinational State of)
ALAFARPE	Asociación Nacional de Laboratorios Farmacéuticos *National Association of Pharmaceutical Laboratories*	Peru
ALIFAR	Asociación Latinoamericana de Industrias Farmacéuticas *Latin American Association of Pharmaceutical Industries*	Argentina (HQ)
AMID	Asociación Mexicana de Industrias Innovadoras de Dispositivos Médicos *Mexican Association of Innovative Industries of Medical Devices*	Mexico
ANL	Asociación de Laboratorios Nacionales *Association of National Laboratories*	Uruguay
ANMAT	Administración Nacional. de Medicamentos, Alimentos y Tecnología Médica *National Administration of Drugs, Foods and Medical Devices*	Argentina
ANRS	Autoridad Nacional de Regulación Sanitaria *National Health Regulation Authority*	Nicaragua
ANVISA	Agência Nacional de Vigilância Sanitária *National Health Surveillance Agency*	Brazil
ARCSA	Agencia Nacional de Regulación, Control y Vigilancia Sanitaria *National Agency for Sanitary Regulation, Control and Surveillance*	Ecuador
ARSA	Agencia de Regulación Sanitaria *Sanitary Regulation Agency*	Honduras
ASEDIM	As. Ecuatoriana de Distribuidores e Importadores de Productos Médicos *Ecuadorian Association of Distributors and Importers of Medical Products*	Ecuador
BDS	Barbados Drug Service *Servicio de Medicamentos de Barbados*	Barbados
BMGF	Bill & Melinda Gates Foundation *Fundación Bill y Melinda Gates*	United States
CAEME	Cámara Argentina de Especialidades Medicinales *Argentine Chamber of Medicinal Specialties*	Argentina
CANIFARMA	Cámara Nacional de la Industria Farmacéutica *National Chamber of the Pharmaceutical Industry*	Mexico
CARPHA	Caribbean Public Health Agency *Agencia de Salud Pública del Caribe*	Trinidad and Tobago (HQ)
CECMED	Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos *Center for State Control of Drugs and Medical Devices*	Cuba
CENARES	Centro Nacional de Abastecimiento de Recursos Estratégicos en Salud *National Center for the Supply of Strategic Health Resources*	Peru
CEPI	Coalition for Epidemic Preparedness Innovations *Coalición para las Innovaciones en Preparación para Epidemias*	Norway (HQ)

Acronym	Organization	Country
CIFABOL	Cámara de la Industria Farmacéutica Boliviana *Chamber of the Bolivian Pharmaceutical Industry*	Bolivia (Plurinational State of)
CIFARMA	Cámara de la Industria Química Farmacéutica del Paraguay *Chamber of the Pharmaceutical Chemical Industry of Paraguay*	Paraguay
CILFA	Cámara Industrial de Laboratorios Farmacéuticos Argentinos *Industrial Chamber of Argentine Pharmaceutical Laboratories*	Argentina
COFEPRIS	Comisión Federal para la Protección contra Riesgos Sanitarios *Federal Commission for the Protection against Sanitary Risk*	Mexico
DIGEMID	Dirección General de Medicamentos Insumos y Drogas *General Directorate of Medicines, Supplies and Drugs*	Peru
DINAVISA	Dirección Nacional de Vigilancia Sanitaria *National Directorate of Sanitary Surveillance*	Paraguay
DNFD	Dirección Nacional de Farmacia y Drogas, Ministerio de Salud *National Directorate of Pharmacy and Drugs, Ministry of Health*	Panama
DNM	Dirección Nacional de Medicamentos *Nacional Directorate of Medicines*	El Salvador
DPM	Directorate of Pharmacy and Medicines, Ministry of Health *Dirección de Farmacia y Medicamentos, Ministerio de Salud*	Haiti
DRCPFA	Departamento de Regulación y Control de Productos Farmacéuticos y Afines *Depart. of Regulation and Control of Pharmaceuticals and Related Products*	Guatemala
EMA	European Medicines Agency *Agencia Europea de Medicamentos*	Netherlands (HQ)
FDA	U.S. Food and Drug Administration *Administración de Alimentos y Medicamentos de los Estados Unidos*	United States
FDD	Food and Drug Department *Departamento de Alimentos y Medicamentos*	Guyana
FIFARMA	Federación Latinoamericana de la Industria Farmacéutica *Latin American Federation of the Pharmaceutical Industry*	Mexico (HQ)
FIOCRUZ/ENSP	Fundação Oswaldo Cruz, Escola Nacional de Saúde Pública *Oswaldo Cruz Foundation, National School of Public Health*	Brazil
IEA	Instituto Especializado de Análisis *Specialized Institute of Analysis*	Panama
ILAR	Asociación Latinoamericana de Autocuidado Responsable *Latin American Association for Responsible Self-Care*	
INCMNSZ	Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán *National Institute of Medical Sciences and Nutrition Salvador Zubiran*	Mexico
INHRR	Instituto Nacional de Higiene Rafael Rangel *National Institute of Hygiene 'Rafael Rangel'*	Venezuela (Bolivarian Republic of)
INQUIFAR	Asociación de Industriales Químico-Farmacéuticos *Association of Chemical-Pharmaceutical Industrialists*	El Salvador
INVIMA	Instituto Nacional de Vigilancia de Medicamentos y Alimentos *National Institute of Drug and Food Surveillance*	Colombia

Acronym	Organization	Country
ISP	Instituto de Salud Pública de Chile *Public Health Institute of Chile*	Chile
MOHW	Ministry of Health and Wellness *Ministerio de Salud y Bienestar*	Jamaica
MoHW	Ministry of Health and Wellness *Ministerio de Salud y Bienestar*	Belize
MPPS	Ministerio del Poder Popular para la Salud *Ministry of Popular Power for Health*	Venezuela (Bolivarian Republic of)
MQCSD	CARPHA Medicines Quality Control and Surveillance Department *Departamento de Vigilancia y Control de Calidad de Medicamentos, CARPHA*	Jamaica
MSF	Médecins Sans Frontières *Médicos Sin Fronteras/Doctors Without Borders*	Switzerland (HQ)
MSPAS	Ministerio de Salud Pública y Asistencia Social *Ministry of Public Health and Social Assistance*	Guatemala
MSPBS	Ministerio de Salud Pública y Bienestar Social *Ministry of Public Health and Social Welfare*	Paraguay
PAHO/WHO OPS/OMS	Pan American Health Organization/World Health Organization *Organización Panamericana de la Salud/Organización Mundial de la Salud*	United States (HQ)
SEDENA	Secretaría de la Defensa Nacional *Secretary of National Defense*	Mexico
SINDUSFARMA	Sindicato da Indústria de Produtos Farmacêuticos *Industry Syndicate of Pharmaceutical Products in the State of Sao Paulo*	Brazil
UASD	Universidad Autónoma de Santo Domingo *Autonomous University of Santo Domingo*	Dominican Republic
UDG	Universidad de Guadalajara *University of Guadalajara*	Mexico
UMC	Uppsala Monitoring Centre *Centro de Monitoreo de Uppsala*	Sweden
UNA	Universidad Nacional de Asunción–Facultad de Ciencias Químicas *National University of Asunción–School of Chemical Sciences*	Paraguay
UNAM	Universidad Nacional Autónoma de México *National Autonomous University of Mexico*	Mexico
UNMSM	Universidad Nacional Mayor de San Marcos *National University of San Marcos*	Peru
USAC	Universidad de San Carlos de Guatemala *University of San Carlos of Guatemala*	Guatemala
USP	United States Pharmacopeia *Farmacopea de los Estados Unidos*	United States
WHO OMS	World Health Organization *Organización Mundial de la Salud*	Switzerland (HQ)

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Melissa Escorihuela	PAHO/WHO	United States
Carissa Etienne	PAHO/WHO	United States
James Fitzgerald	PAHO/WHO	United States
Ileana Fleitas	PAHO/WHO	Mexico
Alexandre Florencio	PAHO/WHO	Nicaragua
Murilo Freitas	PAHO/WHO	United States
Yasmin García	PAHO/WHO	Mexico
Ignacio Ibarra	PAHO/WHO	United States
María Teresa Ibarz	PAHO/WHO	United States
Alexandre Lemgruber	PAHO/WHO	United States
Fernanda Lessa	PAHO/WHO	United States
Cintia Lombardi	PAHO/WHO	United States
Danini Marin	PAHO/WHO	Belize
Alexandra Mata	PAHO/WHO	United States
Pamela Milla	PAHO/WHO	Mexico
Oscar Orantes	PAHO/WHO	Guatemala
Stephanie Ouimet	PAHO/WHO	Canada
Cathy Parker	PAHO/WHO	Canada
Tomás Pippo	PAHO/WHO	United States
María Luz Pombo	PAHO/WHO	United States

Name	Organization	Country
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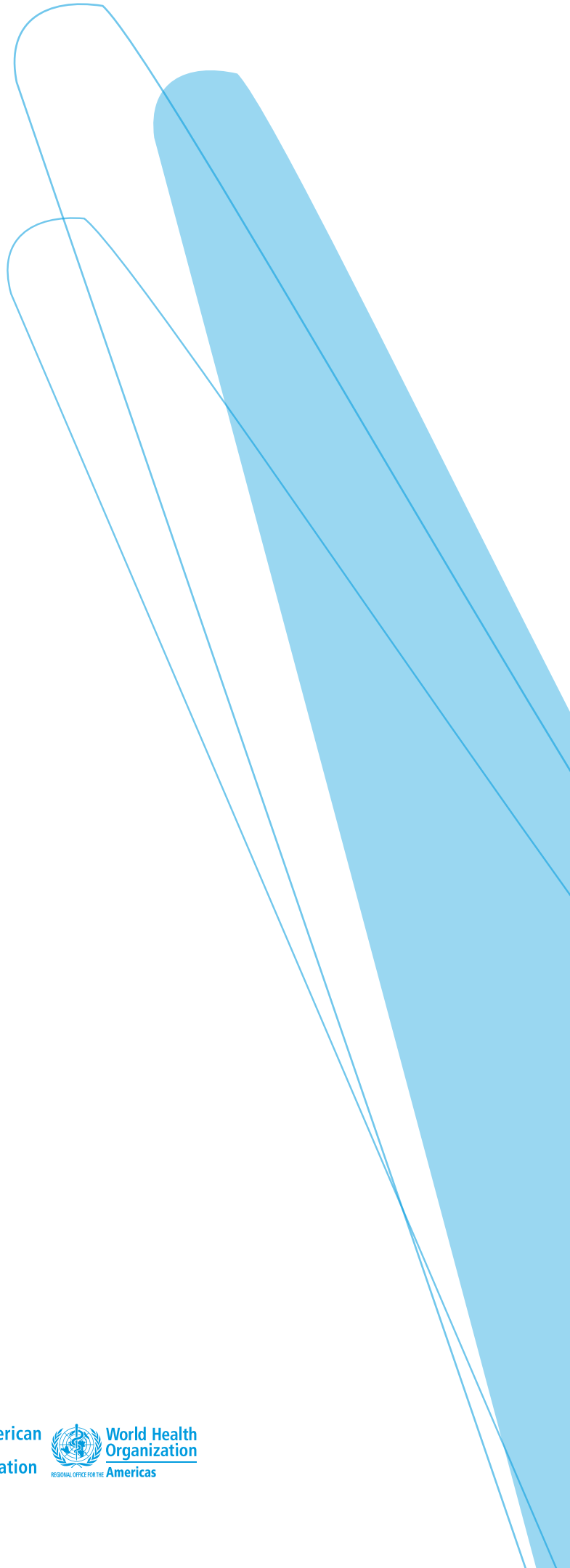
Marcia Quirós	PAHO/WHO	Costa Rica
Ana Ramírez	PAHO/WHO	Honduras
Ugo Ramos	PAHO/WHO	United States
Frank Raposa	PAHO/WHO	United States
Daniel Rodríguez	PAHO/WHO	United States
Robin Rojas	PAHO/WHO	United States
Andrea Rojas Bolaños	PAHO/WHO	Costa Rica
Didia Sagastume	PAHO/WHO	Panama
Begoña Sagastuy	PAHO/WHO	Mexico
Roberto Sánchez	PAHO/WHO	Bolivia (Plurinational State of)
América Valdés	PAHO/WHO	United States
Lou Valdez	PAHO/WHO	United States
Abraham Valles	PAHO/WHO	United States
Natália Veloso	PAHO/WHO	Brazil
Ángela Zambrano	PAHO/WHO	Colombia



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