SECOND AMERICAS RISE FOR HEALTH STATEMENT (RISE II)
PUNTA CANA, DOMINICAN REPUBLIC
11 MARCH 2024

1. We, representatives of governments, private sector, civil society, and academia seeking to harness our collective strengths to build resilient, inclusive, sustainable, equitable health economies and ecosystems, assembled on 11 March 2024, at a meeting chaired by the United States in Punta Cana, the Dominican Republic. We thank the Dominican Republic for its hospitality.

2. We welcome the endorsement of the RISE terms of reference and thank the members of the RISE Steering Committee: The United States, the Dominican Republic, Uruguay, and Panama.

3. We welcome the progress made on advancing the multisectoral collaborations we identified one year ago, when we met on 20 March 2023 in Panama City, Panama, and issued the RISE I statement. We thank all those who contributed to RISE this year across all its pillar workstreams.

4. We reaffirm our unified commitment to identify, catalyze, and accelerate multisectoral collaborations that can be pursued voluntarily to bring about the resilient health ecosystems and economies the Americas deserve.

I. Building resilient, pandemic-prepared health economies and supply chains

5. We are resolved to implement lessons learned from the COVID-19 pandemic, including the need for policies and interventions that ensure resilient, pandemic-prepared health economies and supply chains. To that end, we commit to conducting capacity building and technical cooperation in support of our individual and collective readiness to improve resiliency and security of supply including through procurement practices, such as the inclusion of criteria that go beyond price-only factors and focus on value-based criteria when designing tender bidding procedures.

6. We welcome future work identifying barriers to trade, investment, and national and regional innovation processes for medical products and digital health technologies in our region and analyzing their impact on our people.

7. We reiterate the opportunity for multisectoral efforts to foster cooperation in innovation and knowledge exchange to reduce asymmetries among countries, as well as identify challenges and good practices faced in recruiting, deploying, retaining, and protecting sufficient, well trained, supported, and motivated health workers.

8. We made additional recommendations on how to build capacity for procurement officials to ensure a value-based approach which will be forwarded to the appropriate Working Group for deliberation and consensus decision.

9. We thank Uruguay for leading our efforts to capture more health investment and manufacturing, as well as generate more jobs as part of the health supply chain.

II. Accelerating regulatory improvements

10. We welcome the creation of the *RISE Network for Regulatory Capacity Building* project to strengthen regulatory reliance and convergence across our hemisphere. This network will play a crucial role in supporting regulatory agencies in their decision-making processes, fostering a mutual exchange of expertise and experience among regulators, and promoting investments in the development of skilled talent to ensure the sustainability of these agencies for the future. We extend our appreciation to the U.S. Food & Drug Administration to serving as chair of this Network.

11. We acknowledge the advancement of new medical technologies presents regulatory challenges that require a focus on capacity building. Regulatory systems must adapt and enhance their capabilities to evaluate and regulate these innovations effectively. Promoting capacity building through training programs and knowledge sharing platforms allows regulatory agencies to strengthen their expertise and establish a robust framework. This collaborative approach enables efficient evaluations, timely access to innovative technologies, and enhances patient safety and healthcare outcomes.

12. We look forward to pursuing capacity-building efforts focused on regulatory convergence during 2024 by successfully engaging contributors and participants from regulatory authorities, universities, and industry through internationally recognized standards and guidance. Subsequent capacity building efforts will focus on promoting the implementation of a Common Technical Dossier and its electronic version (e.g. IMDRF ToC for medical devices and in vitro diagnostics, CTD for medicines and vaccines); digitalization of regulatory processes such as electronic submissions; regulatory agility learned from COVID-19; simplified and accelerated pathways for the approval and surveillance of medical products, including self-care products (OTCs) and analyzing reliance practices, regional review models and collaborative procedures.

13. We are also resolved to accelerate regulatory improvements as they relate to medical products by strengthening Good Regulatory Practices, such as those enumerated in the 9th Summit of the Americas on Good Regulatory Practices. To that end, we welcome conducting capacity building in areas such as establishing regulatory agendas, conducting public consultations and regulatory impact assessments, proving reasonable notice of planned regulatory actions and implementation periods, applying risk/scientific-based analyses, using international references and standards as bases for national technical regulations, conducting retroactive reviews, and ensuring the proper legal foundation for rulemaking.

14. We made additional recommendations to ensure that successful regulatory agility measures (e.g. acceptance of digital documents without legalization, simplified labeling and/or e-labeling) taken by regulatory agencies during the COVID-19 pandemic remains, and can be formally adopted in the regulatory frameworks; creating and implementing the use of regulatory sandboxes, when new technology innovations are considered disruptive and required a safe pilot for their review, approval, and adoption; and identifying short-terms policy changes that can be implemented to make a real impact on improving efficiencies, accelerating access and eliminating different standards across the Americas, and we will forwarded it to the appropriate Working Group for deliberation and consensus decision. Another relevant area allowing manufacturing agility to commit to leveraging common standards to promote product harmonization such as packaging harmonization and to optimize product availability providing the medicinal product the registration number at the time of submission application instead of at the end of the review process.

15. We thank Panama for leading our efforts to free up public resources for pressing public health needs, enhance patient access to healthcare, and attract global health investment and manufacturing by accelerating regulatory improvements.

III. Ensuring sufficient, efficient, and equitable health investments

16. Sufficient, efficient, and equitable health investments are required to provide our people with the health services they deserve and to ensure the cost of these services does not create financial hardship. While public financing for health is essential, innovative health financing mechanisms can harness public and private funding sources (e.g., blended finance, impact bonds, novel private insurance). We therefore commit to convening governments, private sector, international development banks, and civil society to build awareness for innovative health financing mechanisms, including those that can help reach our most vulnerable populations. We welcome future work to identify enablers and barriers to those mechanisms for which there is the most interest.

17. We welcome creation of the *RISE Network for Procurement Capacity Building* project to increase awareness and the adoption across the hemisphere of international best practices including those of the World Bank and OECD (Organization for Economic Cooperation and Development) with an objective of improving the use, efficiency, and effectiveness of existing health budgets, and minimizing barriers to patient access, with focus on the access of individuals and groups in situation of special vulnerability and historical discrimination. Working with potential regional partners including the IDB (Inter-American Development Bank), the OAS (Organization of American States), the Inter-American Government Procurement Network (INGP), PAHO (Pan American Health Organization) and the ABD (Americas Business Dialogue), the Network will conduct capacity building to promote adoption of harmonized international guidance and standards, including a focus on Value in Procurement, the World Bank Value for Money (VfM) principles, and piloting work with the medical device and diagnostic sector.

18. We reiterate the opportunity for multisectoral efforts to reinforce public health policies to empower individuals to adopt best self-care practices such as *WHO Guideline on self-care interventions for health and well-being*; enhance understanding of the returns on investments in health and metrics required to make additional investments in health; and share and promote the best investment practices in health from the perspective of equity in the different territories and populations, considering the determinants of health.

19. We thank the Dominican Republic for leading our efforts to ensure that enough financial resources are invested in the health sector and that they are invested efficiently and equitably.

IV. Creating ethical environments in which our health economies can thrive

20. We reiterate the need for opportunities to foster trusted, transparent, accountable, and fair health economies via the adoption of framework consensus agreements for ethical collaboration among stakeholders. These consensus frameworks promote the sharing of best practices while enabling ethical business conduct and preventing corruption therefore supporting an environment in which health economies can thrive. We also welcome the opportunity for multisectoral efforts to reduce corruption in the public procurement processes for healthcare by creating a framework to bolster enterprise integrity in the health public procurement process.

21. We thank the United States for leading our efforts to ensure patients receive the right healthcare at the right time and for the right reasons, while fostering a trusted, transparent, accountable, and fair health economy.

V. Building better health for all communities

22. We reiterate the opportunity for multisectoral efforts to encourage the participation of particularly vulnerable and historically discriminated individuals and groups in regional health dialogues to share perspectives on their unique needs and to support identification of best practices. This includes the implementation of adequate health literacy and the promotion of self-care, including in the areas of differentiated indicators, to ensure the promotion of the health needs for all communities with focus on gender, interculturality and intersectionality.

23. We made additional recommendations referring to the São Paulo Declaration on self-care of November 2023 as a framework for enhancing self-care and contributing to universal health coverage and will forward it to the appropriate Working Group for deliberation and consensus decision.

24. We welcome a government lead for our efforts to create a more just and equitable system that recognizes, measures, and promotes better health for all.

IV. Enabling digital health solutions

25. We reaffirm our resolve to make healthcare more accessible, affordable, and scalable by enabling digital health solutions. To this end, we recognize that diverse digital health definitions and criteria in the region are an impediment to accelerate digital health adoption. We therefore commit to developing an *Americas RISE for Health Digital Health Nomenclature Handbook* project to clarify and harmonize definitions and criteria with international standards to enable digital health adoption. We look forward to convening a forum to ensure discussion and collaboration with regulators, relevant standards bodies, and global experts to develop the nomenclature handbook.

26. We endorse a *RISE Digital Health Roadmap* project that encompasses a step-by-step process to improve fit-for-purpose regulatory frameworks and national digital health policies & plans in the region. This includes multisectoral efforts to: develop appropriate policies, privacy practices, and cybersecurity frameworks to protect personal health data while removing unnecessary barriers (e.g., data localization and sovereignty requirements) to cross border data transfers; encourage measures and fit for purpose regulatory frameworks that enable the use of digital health solutions; and promote modernized, scalable information technology systems, such as public cloud services, interoperability and artificial intelligence; and exchange best practices for the development of basic infrastructure needs for digital health (e.g., electricity and internet coverage), especially for those communities with limited access; and combat health misinformation.

27. We made additional recommendations on ensuring proper resources allocation that enables digital health adoption and implementation, immediate access to qualified wellbeing professionals, innovative programs for raising digital health awareness, and practical resources for organizations to implement local programs that spur digital health adoption, which will be forwarded to the appropriate Working Group for deliberation and consensus decision.

28. We thank Uruguay for leading our efforts to make healthcare more accessible, affordable, and scalable by enabling digital health solutions in the region.

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29. We thank the Dominican Republic for hosting the second annual RISE meeting and look forward to reviewing progress when we meet again in 2025.

Participants

Government	Private Sector/Civil Society/Academia
Argentina	ABIIS - Aliança Brasileira da Indústria Inovadora em Saúde
Brasil	Access Partnership
Colombia	Accumed by Lear
Dominican Republic	Advanced Medical Technology Association (AdvaMed)
Ecuador	Amazon Web Services
Guatemala	Amcham Dominican Republic
Guyana	Americas Business Dialogue
Panama	ARS Primera
United States	Asociacion Kunas Unidos por Nabguana (KUNA)
Uruguay	Atlantic Council
	BOMI UPS Healthcare
	Centro de la Mujer Panameña (CEMP)
	Chamber of Pharmaceutical Innovation
	Citizen Forum of America
	Consejo Nacional de Zonas Francas
	Corporación Industria Farmacéutica de Investigación
	Council of the Americas
	Eli Lilly & Company
	Ethicist International
	Fedefarma
	FIFARMA
	Fundación para la Transparencia institucional
	Ginkgo Bioworks
	Haleon

	ILAR
	Inter-American Coalition for Business Ethics – Medical Technology Sector (IACBE)
	Inter-American Coalition for Regulatory Convergence – Medical Technology Sector (IACRC)
	Interfarma
	Johnson & Johnson
	Kenvue
	Medtronic
	Merck & Co.
	Moonlight International
	Northeastern University
	Novartis
	Organon
	Pharmaceutical Innovation Association of Mexico (AMIIF)
	REDLAD
	Roche Diagnostics
	Sanofi
	Transparencia Venezuela
	USC, DK Kim International Center for Regulatory Science
	U.S. Chamber of Commerce
	U.S. Pharmacopia
	UPS Healthcare
	Vision Americas International
	Workplace Options