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POLICY TO STRENGTHEN NATIONAL REGULATORY SYSTEMS FOR MEDICINES AND OTHER HEALTH TECHNOLOGIES

Introduction

1. Equitable access to safe, effective, and quality medicines and other health technologies[1] is a prerequisite for achieving universal health. The regulatory system is an essential component of the health system and is responsible for the regulation and oversight of medical products to ensure they meet safety, efficacy, and quality standards to further equitable access and contribute to economic and social development.

2. Strengthening regulatory systems remains a public health priority for the Member States. In 2010, the Region of the Americas adopted a system for evaluating and qualifying regulatory systems and systems for recognizing national regulatory authorities (NRAs) of regional reference. The objective of this policy is to renew the mandates, considering the achievements and new challenges confronting the Region in the regulation of all medical products of interest to the health system, as well as the potential role of regulatory systems in promoting the production of health technologies and responding to health emergencies.

Background

3. In 2000, the Member States of the Pan American Health Organization (PAHO), through Resolution CD42.R11, approved the creation of the Pan American Network for Drug Regulatory Harmonization (PANDRH) *(1)* with the object of supporting harmonization processes consistent with national and subregional health situations and

[1] The term *medicines and other health technologies* used here covers medical products such as pharmaceuticals, biologics, and diagnostic medical devices. Furthermore, according to World Health Assembly Resolution WHA60.29, the term *health technologies* refers to "the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of lives". Therefore, for the purposes of this document, the terms *health technologies* and *medical products* will be used interchangeably to refer to these categories.

policies, once existing asymmetries had been recognized.[2] In 2010, the Member States adopted Resolution CD50.R9 Strengthening National Regulatory Authorities for Medicines and Biologics *(2)*, which urged the countries to strengthen regulatory capabilities to ensure that medicines and biologics meet internationally recognized standards of quality, safety, and efficacy, and requested the Director of the Pan American Sanitary Bureau (PASB) to provide support for the development of a qualification system for NRAs with a view to strengthening them. In 2013, PANDRH adopted a new operational model *(3, 4)*,[3] and in 2018 added medical devices to its priorities. In 2014, the 67th World Health Assembly adopted resolutions WHA67.20, Regulatory System Strengthening for Medical Products *(5)*, and WHA67.21, Access to Biotherapeutic Products and Similar Biotherapeutic Products and Assuring Their Quality, Safety, and Efficacy *(6)*, which urged the Member States to strengthen and evaluate their regulatory systems, facilitate international regulatory cooperation, and strengthen regulatory frameworks for these products, among other measures.

4. Today, the countries face new challenges to the construction of efficient, integrated regulatory systems and must consider the new regional and global context, the specific aspects of the regulation of different health technologies, the demand in health emergencies, and the search for greater efficiency through use of the regulatory decisions in other jurisdictions (known as *reliance*).[4] The global adoption in 2019 of the WHO Global Benchmarking Tool for Evaluation of National Regulatory System of Medical Products (GBT) *(7)*, which classifies regulatory systems by their maturity level, and the World Health Organization's designation of NRAs as WHO-listed authorities (WLA) *(8)* require renewed regional mandates. Moreover, the Sustainable Health Agenda for the Americas 2018-2030 *(9)* and the PAHO Strategic Plan 2020-2025 *(10)* establish that Member States' regulatory systems should reach maturity level 3, as measured by the WHO Global Benchmarking Tool, by 2030. Finally, several recent mandates establish that strengthening regulatory systems is critical to improving affordability, availability, and ultimately, equitable access to health technologies, and to the development of the productive sector and the response to health crises *(11-15)*.

Situation Analysis

5. The experience of the past decade shows that the Region has taken a successful approach to strengthening regulatory capacity. Through a pioneering program for evaluating and strengthening medicines and vaccine regulatory systems, PASB has evaluated more than 75% of the Region's regulatory systems with a standardized tool to

[2] The NRAs, industry, and other major actors in the Region are represented in PANDRH. PAHO serves as its permanent technical secretariat.

[3] The new statutes are aimed at strengthening governance of the network, prioritizing the development of needs-based technical standards, boosting regional capacity in science and good regulatory practices, supporting human resource development, and facilitating information exchange among NRAs.

[4] According to WHO, this is action whereby the NRA of one jurisdiction can consider and give significant weight to (that is, fully or partially utilize) evaluations conducted by another NRA or reliable institution when making its own decision.

determine their strengths and opportunities for improvement *(15)*.[5] This program made it possible not only to support countries in strengthening their regulatory systems but also to identify eight NRAs of regional reference according to their degree of functionality.[6] Together, the systems overseen by these NRAs of regional reference provide coverage to 82% of the Region's population and have some of its most active health technology markets *(15, 16)*. Also worth noting is the creation of new NRAs as part of the strengthening efforts *(17-21)*, as well as the creation of institutional development plans in 32 countries.[7]

6. The new subregional or multinational approaches have strengthened regulatory capacity in countries with challenges inherent to small pharmaceutical markets *(22)*. In 2016, the ministers of health of the Caribbean Community launched the Caribbean Regulatory System (CRS) under the Caribbean Public Health Agency (CARPHA) *(23)*. Recently, some of the NRAs in Central America launched a joint drug evaluation mechanism aimed at accelerating the availability of quality medicines, increasing efficiency, and promoting better use of resources in the subregion[8] *(24, 25)*.

7. The Region has also made progress in regulatory convergence and harmonization. PANDRH has revamped its work model and implemented projects devoted to solving common problems for specific regulatory functions and health technologies. The participation of the Region's NRAs in international harmonization mechanisms has also increased. The designation of NRAs of regional reference has accelerated recognition of the decisions of these authorities in the Region and beyond *(16)*.

8. Despite the progress, significant challenges and asymmetries persist in the Region. The eight NRAs of regional reference (23%) have yet to adopt continuous improvement plans to meet new demands and cover all health technologies. Thirteen Member States (37%) have regulatory systems that perform all the functions recommended by WHO but have not attained the desired functionality, while seven (20%) do not perform at least one of them; the remaining seven Member States (20%) do not perform multiple functions and lack the necessary legal underpinnings or organizational structures *(16)*. Furthermore, in most of the evaluated NRAs, there are weaknesses in certain functions, such as market surveillance and control.

[5] Regular monitoring and evaluation of implementation and progress in institutional development plans are also based on these evaluations. The results of the evaluations are available to participating regulatory bodies and are published through the Regional Platform on Access and Innovation for Health Technologies (PRAIS), an online collaboration platform.

[6] In 2019, the NRAs of regional reference were: the National Administration of Drugs, Foods, and Medical Devices (ANMAT), Argentina; the National Health Regulatory Agency (ANVISA), Brazil; the Center for State Control of Medicines and Medical and Devices (CECMED), Cuba; Federal Committee for Protection from Sanitary Risks (COFEPRIS), Mexico; Health Canada, Canada; Institute of Public Health, Chile; National Food and Drug Surveillance Institute (INVIMA), Colombia; Food and Drug Administration (FDA), United States of America.

[7] Since 2010, Ecuador, El Salvador, Honduras, Nicaragua, and Paraguay have created new authorities.

[8] The participating countries (Costa Rica, Guatemala, Honduras, and El Salvador) jointly review and evaluate product documentation in order to issue marketing authorization and conduct post-marketing surveillance of strategic products.

9. Although there is no single model for developing an effective and efficient regulatory system, PAHO and WHO recommend a series of principles, elements, and functions to consider *(7, 26)*. The most effective NRAs are characterized by legal and organizational frameworks that give them technical independence and a strong mandate for oversight and enforcement in the regulated sector. They also recognize the value of harmonization initiatives and encourage the adoption of international standards.[9] In contrast, NRAs with more limited capacity tend to have a lower position in the health system and limited enforcement power, in addition to applying weaker or outdated standards.

10. As indicated in the 2021 report *(16)*, regulatory systems do not always have the resources necessary to operate and meet growing market demand. For example, the fiscal budgetary allocations for Latin America's NRAs of regional reference for the period 2015-2019 remained relatively stable, while the market to be regulated grew substantially *(16)*. The adoption of reliance practices can boost efficiency and save resources in all regulatory systems, regardless of their installed capacity, in addition to extending capacities beyond the national territory. However, Member States should follow the principles adopted by the Ninth PANDRH Conference and the good reliance practices adopted by the WHO Expert Committee on Specifications for Pharmaceutical Preparations *(27, 28)* to ensure that these practices do not lower the quality of health technologies.[10]

11. Gaps persist in the transparency of regulatory decisions, despite the increase in digital publication of the results of regulatory processes by NRAs. Furthermore, there are still problems related to information exchange and the availability of public information that would allow for the adoption of reliance practices, identification of the origin of products, and deviations detected in market surveillance.

12. Regulatory systems must regulate and oversee all health technologies pertinent to the health system, employing benefit-risk criteria. Medical devices require special consideration, since their enormous variety and multiple origins pose many challenges to their regulation. Medical devices are essential goods for health promotion and for disease prevention and treatment, and palliative care. PASB's participation as an affiliate organization of the International Medical Device Regulators Forum (IMDRF) and the creation of the Regional Working Group on Medical Device Regulation have facilitated progress in regulating these products in the Region.[11] However, in 2020, only five of

[9] Argentina, Brazil, Canada, Mexico, and the United States of America are part of the Pharmaceutical Inspection Cooperation Scheme (PIC/S); Brazil, Canada, Mexico, and the United States of America are members of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), in which Argentina, Colombia, and Cuba are observers; Canada, Chile, Mexico, Peru, and the United States of America are members of the Asia-Pacific Economic Cooperation Forum (APEC); and Brazil, Canada, and the United States of America are members of the International Medical Device Regulators Forum (IMDRF), in which Argentina is an official observer.

[10] These principles are the basis for WHO guidance in the 2021 document.

[11] This Regional Working Group was formed in 2012 to strengthen regulatory capacity in relation to medical devices. As of 2022, this group of 25 Member States had created groups similar to the IMDRF, supported training courses and the drafting of technical documents, and agreed on indicators and evaluations for measuring regulatory capacity.

22 NRAs met 90% of the basic capacity measurement indicators, 11 met at least 75% of them, and another 5 met less than 50%.[12] Similarly, regulatory systems should exercise their responsibility for verifying the quality, safety, and efficacy of blood and blood products through regulatory frameworks and monitoring of the collection, processing, and administration of blood and its components, as well as plasma intended for fractionation *(29)*.[13] In most countries, blood services are overseen exclusively by the ministry of health to verify the quality of transfusion products but not of products that enter the production system. Likewise, heterogeneity and weaknesses persist in the regulation of generic or multisource products and biosimilars *(6, 30)*.[14] The Ninth PANDRH Conference adopted recommendations on the regulation of advanced cellular therapeutics and personalized products, as most regulatory systems do not yet have appropriate regulations *(31)*. The regulation of products intended for use in traditional medicine is an issue that must be considered in countries where such practices prevail.

13. Post-marketing surveillance is a weakness in the Region's regulatory systems.[15] These surveillance functions tend to be less prioritized and have fewer resources allocated *(16*), and coordination gaps in their implementation between NRAs and other actors in the system persist. For example, in Latin America, only Brazil and Colombia have national hemovigilance programs with extensive coverage of blood services. Many NRAs have difficulty in assuming responsibility for managing events supposedly attributable to vaccination and immunization (ESAVI), and structural, reporting and coordination problems with immunization programs persist.[16] Also, despite the creation of the Exchange of Reports on Adverse Events of Medical Devices (REDMA) program, gaps in technovigilance still persist, and only 13 out of 22 countries report that they have legal measures governing the technovigilance of medical devices.[17]

[12] Data from PAHO's "Regional Mapping of Medical Device Regulation" survey, which collected data from 22 countries in 2020 and covered the following topics: human resources, good regulatory practices, national regulatory systems, import control, marketing authorization, post-marketing surveillance, regulatory inspections, testing laboratories, clinical research, and in vitro diagnostic devices.

[13] Blood products include whole blood and blood components for direct transfusion in patients—that is, cellular components (red blood cells and platelets), plasma, and cryoprecipitate. Blood products also include protein concentrates obtained from plasma or plasma-derived medicinal products. Furthermore, fractionated plasma and other blood components are used as basic materials for the manufacture of blood products.

[14] The WHO uses the term *multisource pharmaceutical product* and defines it as a pharmaceutical equivalent or alternative that may or may not be a therapeutic equivalent. Multisource pharmaceutical products that are therapeutically equivalent are considered interchangeable *(39)*.

[15] For the purposes of this document, post-marketing surveillance includes pharmacovigilance, technovigilance, and hemovigilance, in addition to market oversight and control.

[16] Many Member States do not reach the minimum threshold of 200 annual adverse event reports per million population or do not notify the WHO Collaborating Centre for International Drug Surveillance in Uppsala. Fewer than 18 Member States have reported ESAVIs associated with COVID-19 vaccines to this Collaborating Center. Data from the 2021 *Regional Survey on the State of ESAVI Surveillance Information Systems* (forthcoming).

[17] REDMA, a program for the exchange of notifications of adverse events associated with medical devices in the Region of the Americas, is a joint initiative of PAHO and CECMED, a PAHO/WHO Collaborating Center on the regulation of health technologies, within the framework of activities of the Regional Working Group on Medical Device Regulation. The data are available in PRAIS.

14. Substandard and falsified medical products pose an unacceptable health risk *(32).* The countries of the Region spearheaded the creation of the WHO Member State mechanism on substandard and falsified medical products and, over the past five years, have significantly increased incident reporting through the WHO Global Surveillance and Monitoring System *(33).* Internet sales increase the challenge and require new regulatory frameworks and detection and response strategies *(34).* Solutions that allow for the traceability of products throughout their entire life cycle and working in networks are extremely valuable in fighting substandard and falsified medical products, as well as in post-marketing surveillance.[18]

15. Over-the-counter sales of antibiotics remains a common practice in Latin America and the Caribbean, with the consequent health risks and contribution to antimicrobial resistance, despite the fact that the majority of Member States have regulations on the dispensing of antibiotics under prescription and some have taken steps to enforce them.[19]

16. In Latin America and the Caribbean, there are delays in updating and implementing the inspection standards recommended by WHO in relation to good manufacturing, clinical, and storage and distribution practices. Moreover, Member States continue to rely heavily on imports of products and raw materials and do not always have the necessary means to control the quality of imported substances. Regulatory inspections conducted locally or in other countries are not always based on benefit-risk criteria, and there is opportunity to use the decisions of other reliable jurisdictions to guarantee the quality of all manufacturing components. In addition, the integrity of supply chains is threatened by weaknesses in the verification of good storage and distribution practices (*35*) throughout the product lifecycle. For example, in the biennium 2020-2021, PAHO recorded more than 200 events related to deviations in the storage conditions for biologics.[20]

17. Strengthening regulation in health technology-producing countries is a high-yield investment, and the application of international standards has a positive impact on export prospects *(16)* and eligibility for WHO prequalification and United Nations procurement systems *(8).*[21]

[18] There are regional NRA networks for both pharmacovigilance and the prevention, detection, and response to substandard and falsified medical products. The 35 Member States share information to strengthen the detection and reporting of adverse events, as well as the calculation of risks and benefits.

[19] A total of 21 out of 23 countries in Latin America and the Caribbean in 2015 and 15 out of 18 countries in Latin America in 2020 reported that antibiotics could be purchased without a prescription despite regulations to the contrary. Data taken from *Lines of action and indicators for the rational use of medicines and other health technologies* (forthcoming).

[20] It is estimated that these events affected the quality of more than 1 million doses of vaccines and entailed an estimated loss of more than US$ 1.4 million, and that that number represents only a portion of the total deviations that occurred in the Region during this period.

[21] Since 2016, products authorized, marketed, and inspected by NRAs of regional reference are eligible for purchase through PAHO's revolving funds (*36*). In addition, WHO has recognized the functionality or regulatory capacity of NRAs in the prequalification programs for medical products since their inception: vaccines (1987), in vitro diagnostics (1988), and medicines (2001) *(37).*

18. Despite an increase in the number of clinical trials in Latin America and the Caribbean, many countries have limited capacity to oversee and monitor them. In 2019, 11 of the 35 Member States had legal measures in place for the authorization and oversight of clinical trials that did not comply with WHO recommendations *(16)*.

19. Regulatory systems play key roles in public health emergencies, but countries do not always have regulatory plans for these situations: in 2018, 15 out of 16 Member States reported that they had adopted a national pandemic influenza plan that included regulatory preparedness, but only 31% had verified its functionality. In addition, six of 16 Member States indicated that they did not have a plan to ensure the availability of essential products during a pandemic *(38)*. Faced with the COVID-19 pandemic, NRAs adopted measures to address regulatory issues surrounding access to essential technologies. In April 2020, PASB created a network to detect and overcome pandemic-related regulatory obstacles and promote timely information exchange among NRAs.[22] Thanks to the introduction of emergency regulatory measures and reliance on the decisions of other jurisdictions regarding the introduction of essential products, Member States did not report regulatory delays in the entry of essential inputs for the COVID-19 response. WHO recommendations on the use of vaccines from the Emergency Use Listing, facilitation of the Member States' access to evaluation reports on these vaccines, and implementation of accelerated procedures or exemptions to authorize the entry of products purchased through PAHO's revolving funds *(39)* were essential to the acceleration and efficiency of regulatory authorizations in the countries. However, the effort to facilitate more flexible regulatory measures for the emergency has sometimes put pressure on NRAs to relax supervision and control measures. Safeguarding the technical independence of NRAs is critical to unbiased decisions consistent with good regulatory practices and for monitoring product performance during emergencies to prevent the use of products of dubious effectiveness or substandard quality.

20. As indicated above, in 2015 the WHO Member States supported the adoption of a single tool and methodology (the GBT tool) to comparatively evaluate all regulatory systems, identify gaps, and strengthen the systems. The Region of the Americas played an active role in defining this global strategy and designing this tool. Furthermore, the designation of authorities on the WHO listing will make it possible to identify reliable regulatory systems, promoting reliance on the decisions of other jurisdictions and boosting the efficiency of the prequalification and procurement system. WHO is currently designing a transition to the new system *(40)*, which will have an impact on international qualification of the Region's NRAs.[23]

[22] In 2020, the NRA pandemic response focal point network provided PAHO with information on existing regulatory mechanisms for the COVID-19 response. The information exchanged in the network was made available to more than 750 users in an exclusive community of practice created in PRAIS with PAHO support. As of December 2021, at more than 30 meetings, the sharing of practices for the pandemic response and information on products included in the WHO Emergency Use Listing, among other activities, was promoted.

[23] As part of the shift in the use of the term *stringent regulatory authority* (SRA) for WHO-listed authority (WLA). WHO published a provisional five-year listing that includes the following entities: 1) regulatory uthorities considered to be stringent NRAs prior to the ICH reform of 2015; 2) NRAs of regional reference in the Americas; 3) NRAs that have reached maturity level 3 or 4 after evaluation with the WHO global tool; 4) Functional NRAs for the regulation of vaccines evaluated by WHO before 2016; and 5) high-performance NRAs for vaccine regulation. This list is available at: https://cdn.who.int/media/docs/default-source/medicines/regulatory-updates/wla/list-of-transitional-wlas.pdf.

Proposal

21. The objective of this policy is to promote efficient regulatory systems in all Member States, tailored to the needs of their health systems, with a maturity level of 3 or higher in order to ensure the quality, safety, and efficacy of health technologies, in keeping with PAHO/WHO recommendations.[24] In addition, where national policies are in place and the context permits, regulatory systems can help foster the production of health technologies that promote equitable access, health and well-being, and economic and social development.

Adopt sustainable State policies to strengthen the governance and stewardship of regulatory systems

22. Strengthening regulatory systems requires time, resources, and a sustained commitment. Consolidating a regulatory system requires the designation of an NRA that conducts, coordinates, and facilitates the integration of its components. This coordination must be formalized through legal measures and translated into transparent and efficient mechanisms for joint work, both in routine and crisis situations. In addition, NRAs need to occupy a high position in the national health system and require a strong mandate for oversight and enforcement in their territories. Technical independence, equity, transparency, ethics, a code of conduct, absence of conflicts of interest, risk management, accountability, and application of regulatory science are the principles that should guide NRA activities. The legal underpinnings for performing their functions are a cross-cutting element necessary to perform their functions, along with standards, guidelines, specifications and procedures, funding and other resources, quality assurance, information systems, and competent human resources *(26)*.

Promote the strengthening of regulatory systems to ensure consistent, transparent processes based on regulatory science

23. The application of standards based on regulatory science recommended by WHO strengthens regulatory systems and promotes health, people's trust, and support for the industrial sector. NRAs should adopt continuous improvement plans and strategies to perform the WHO recommended functions *(7)*, covering the entire product life cycle, global supply chains, and health emergencies, including waste disposal and environmental responsibility. In all cases, priorities should be based on a benefit-risk assessment and the needs of the health system. Moreover, strengthening plans must recognize and consider specific aspects of the regulation of different health technologies, including drugs, devices, or other technologies.

24. Subregional or multinational initiatives, such as the Caribbean Regulatory System or the Mechanism for the Joint Evaluation of Medicines in Central America, should be

[24] According to the WHO Global Benchmarking Tool, the maturity of regulatory systems is assessed on a scale of 1 to 4. Maturity level 3 denotes a stable, well-functioning, integrated regulatory system, and maturity level 4, a regulatory system that operates with a high level of performance and continuous improvement.

strengthened to enable Member States to achieve greater regulatory maturity. Participating countries should redouble their efforts to strengthen these mechanisms, increase their use, and create synergies with national authorities.

25. Beyond the exercise of their regulatory functions, regulatory systems can contribute to improving industrial ecosystems by fostering an environment of predictability and regulatory oversight in countries with domestic production and by assuming responsibility for the regulation and control of locally manufactured products throughout their life cycle. The manufacture of medical products requires regulatory systems to perform all the regulatory functions recommended by WHO, without delegating them, to guarantee the quality, efficacy, and safety of these products and build trust in them.

Strengthening regulatory harmonization and convergence

26. A globalized market for medical products requires international cooperation for effective regulation and supervision. National regulations should cover supply chains that include production plants and active ingredients from other jurisdictions with varying degrees of oversight. NRAs can increase their effectiveness both within their jurisdictions and beyond by exchanging information, sometimes sharing tasks, and in many cases, relying on the use of decisions from other trusted jurisdictions. Regulatory systems should encourage creation of the necessary agreements and mechanisms to allow for this exchange of information.

27. Robust regulatory systems and the harmonization of regulatory standards can minimize legal barriers to accessing essential medical products, including vaccines, during a health emergency. Given the challenges facing the countries during the COVID-19 pandemic, there is an urgent need to strengthen regulatory systems before the next widespread health emergency occurs.

28. Increased collaboration through PANDRH and other networks on specific health issues and technologies, as well as participation in international harmonization and convergence mechanisms, can substantially boost regulatory capacity in the Region and facilitate adoption of WHO recommended standards and the exchange of information for regulatory decision-making.

29. Promoting the transparency of regulatory decisions through digital publication of all aspects relevant to a clear understanding of the grounds for decisions, and providing information, in collaboration with the industrial sector, that confirms the origin of products and whether they correspond to the versions authorized in other markets, are requirements for convergence and for facilitating reliance on decisions from other jurisdictions. Among other aspects, these are factors that will build trust and promote regulatory efficiency.

Adopt new evaluation systems based on the WHO Global Benchmarking Tool (GBT) and related mechanisms

30. The evaluation and qualification system used by PASB will be updated to align it with the new WHO Global Benchmarking Tool. PAHO will reactivate the mechanism for

evaluating and qualifying regulatory systems to strengthen them through an institutional development plan aimed at reaching maturity level 3 or higher. If any Member State believes its regulatory authority can be designated a WHO listed authority, PAHO will coordinate with the respective WHO programs to initiate the process. Designation as a WHO listed authority will make products from markets overseen by these authorities eligible for purchase through PAHO's revolving funds once the transition period has concluded.

31. In addition, cooperation and coordinated technical assistance will be promoted among NRAs to address asymmetries in the maturity of regulatory systems and to increase expertise, information exchange, and participation until the projected maturity levels and their sustainability are reached.

Monitoring and Evaluation

32. Implementation of the recommended actions is expected to be monitored through consultations and joint work with the NRAs. The evaluation of regulatory systems and the adoption of institutional development plans in keeping with the new international methodologies are also expected.

33. This policy will remain in effect until it is replaced, and a progress report will be submitted to the Governing Bodies every five years.

34. This policy will contribute to the achievement of Outcome 8 of the PAHO Strategic Plan 2020-2025 (Access to health technologies) and will therefore also be reported in the respective monitoring and evaluation reports.

Financial Implications

35. Annex B, "Report on the Financial and Administrative Implications of the Proposed Resolution for PASB", provides detailed information on the financial resources required for this policy. The analytical form linking the agenda item to the institutional mandates is also attached as Annex C.

Action by the Pan American Sanitary Conference

36. The Conference is invited to review the information presented in this document, make any comments it deems pertinent, and consider approving the proposed resolution in Annex A.

Annexes

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Pan American Health Organization
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30th PAN AMERICAN SANITARY CONFERENCE

74th SESSION OF THE REGIONAL COMMITTEE OF WHO FOR THE AMERICAS

Washington, D.C., USA, 26-30 September 2022

CSP30/11
Annex A
Original: Spanish

PROPOSED RESOLUTION

POLICY TO STRENGTHEN NATIONAL REGULATORY SYSTEMS FOR MEDICINES AND OTHER HEALTH TECHNOLOGIES

THE 30th PAN AMERICAN SANITARY CONFERENCE,

(PP1) Having reviewed the document Policy to Strengthen National Regulatory Systems for Medicines and Other Health Technologies (Document CSP30/11);

(PP2) Recognizing that regulatory systems are an essential component of the health system and must address its needs, including the creation of efficient regulatory response mechanisms for health emergencies;

(PP3) Considering the progress made since the creation of the Pan American Network for Drug Regulatory Harmonization (PANDRH) and the adoption in 2010 of Resolution CD50.R9 on strengthening regulatory systems for medicines and vaccines, collaborating and seeking greater efficiency for harmonization and regulatory convergence, and the implementation of new subregional and multinational approaches to the subject;

(PP4) Considering the regional successes achieved through the implementation of a pioneering program for evaluating and strengthening regulatory systems for medicines and vaccines, the drafting of evidence-based institutional development plans, and the designation of eight national regulatory authorities of regional reference, as well as international progress toward implementation of a single global tool for the evaluation of regulatory systems and of the requirements for the inclusion of national regulatory authorities in the World Health Organization (WHO) listing;

(PP5) Recognizing that countries today face new challenges in the construction of efficient, integrated health regulatory systems that respond nimbly to changing contexts and health emergencies and in the development or expansion of existing capacities to regulate and oversee the various health technologies essential to health systems,

RESOLVES:

(OP)1. To approve the document Policy to Strengthen National Regulatory Systems for Medicines and Other Health Technologies (Document CSP30/11).

(OP)2. To urge the Member States, in keeping with their contexts and needs, to:

a) adopt sustainable State policies with a view to strengthening regulatory system governance and stewardship to ensure the efficacy, safety, and quality of health technologies that enter the health system and promote access to them;

b) encourage regulatory systems to contribute to the development and manufacture of health technologies and the creation of industrial ecosystems, promoting an environment of predictability and regulatory oversight in countries with domestic production, and assuming responsibility for regulating and overseeing locally manufactured products throughout their life cycle;

c) adopt frameworks for the construction of regulatory systems consistent with health systems and the industrial sector, designating and strengthening a national regulatory authority (NRA) to perform essential regulatory functions and coordinate the members of that regulatory system, where appropriate, through formal, transparent, and efficient mechanisms based on good regulatory practices, both in routine situations and health crises;

d) position NRAs at a high level within the health system, supported by sound legal underpinnings, funding, competent human resources, and physical resources to regulate and oversee health technologies;

e) ensure that regulatory systems have technical independence, promote equity, and act transparently and without bias, in accordance with ethical principles and without conflicts of interest, guided by regulatory science and based on risk-benefit assessments;

f) ensure effective regulation and oversight of all medical products of interest to the health system, including those used in traditional medicine when the context so requires, ensuring their quality, safety, and efficacy throughout their life cycle;

g) strengthen subregional and multinational regulatory initiatives, seeking synergies among participating NRAs to ensure greater efficiency and complement and enhance the development of regulatory functions in resource-limited contexts;

h) promote harmonization and regulatory convergence through participation in PANDRH and the international harmonization mechanisms recommended by the Pan American Health Organization (PAHO) and World Health Organization (WHO) as sources of regulatory standards and good practices, including mechanisms such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the International Medical Device Regulators Forum (IMDRF), and the Pharmaceutical Inspection Co-operation Scheme (PIC/S);

i) promote transparent regulatory decision-making and information exchange among countries as a requirement for convergence, harmonization, and reliance on regulatory decisions from other jurisdictions, especially in cases where this makes it possible to verify the origin and provenance of products and their correspondence with the versions authorized in other markets;

j) encourage the industrial sector to contribute to and promote transparency in the regulated market by removing obstacles to the exchange of regulatory information between countries, publishing regulatory decisions, and contributing to the identification and characterization of products entering health systems;

k) promote trust in regulatory decisions and the quality of regulated products by combating misinformation and disinformation, and duly publish and communicate the grounds for regulatory decisions to the public and the regulated sector;

l) promote and consolidate, with other relevant domestic actors, the international reporting of the results of post-marketing surveillance and control activities, such as the reporting of adverse events to the WHO Collaborating Centre in Uppsala and incidents to the WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products;

m) adopt procedures for the continuous strengthening and improvement of regulatory systems that include plans for continuous training of human resources, in keeping with the national context, based on monitoring and evaluation of their capacities, using the WHO Global Benchmarking Tool for the evaluation of regulatory systems;

n) participate in, promote, and support the definition of tools and the formal evaluation of regulatory systems led by PAHO/WHO, ensuring the transparency of evaluation results and qualifications, and making a commitment to promote the progress and performance of regulatory systems in the Region that have more limited capacities, and the adoption of practices for reliance on decisions from other jurisdictions to achieve regulatory goals;

o) promote coordination of the regulatory system, health programs, and institutions relevant to emergency preparedness in health; the reporting, investigation, and review of events related to the safety, efficacy, or quality of medical products; and the surveillance of substandard or falsified medical products, among other aspects;

p) adopt regulatory plans for pandemic preparedness that include ways to increase the efficiency of regulatory procedures and improve international communication and collaboration, and put effective surveillance systems in place for products used during emergencies;

q) strengthen information and digitization of systems that facilitate the search for more efficient regulatory procedures, greater transparency, and dissemination of the results of regulatory measures and decisions, as well as the exchange of information between entities that are part of the domestic and subregional regulatory system and international collaboration.

(OP)3. To request the Director to:

a) provide Member States with technical support to implement this policy to strengthen regulatory capacities, with emphasis on countries with structural challenges or more limited regulatory capacities, as well as those wishing to improve ecosystems for domestic production through regulatory capacity building, including human resources training;

b) strengthen and update the PAHO/WHO program for the evaluation of regulatory systems by implementing the new strategies agreed to by the WHO Member States and using the new WHO Global Benchmarking Tool for Evaluation of National Regulatory System for Medical Products (GBT) and related methodologies, and advocate for international recognition of the progress made in strengthening regulatory systems in the Region, as well as the development of new modules on medical devices and other technologies that take into account the specific characteristics of these products;

c) define the procedures, requirements, and timeframes for transition to the new system for designating NRAs of regional reference; promote adoption of the globally recognized system for designating regulatory authorities; and update product eligibility for purchases made through the Revolving Fund for Vaccine Procurement, the Regional Revolving Fund for Strategic Public Health Supplies, and other PAHO procurement mechanisms, in line with those designations;

d) provide technical support for strengthening regional regulatory harmonization and convergence networks and technical working groups, especially PANDRH, buttressing PAHO's role as technical secretariat of the network;

e) encourage the exchange, dissemination, and use of data on the safety, quality, and falsification of medical products, using the regional and global tools recognized by PAHO/WHO and involving the community;

f) provide support for countries to develop or strengthen communication systems that enable regulatory systems to operate online, in order to increase the efficiency of pre- and post-marketing procedures and facilitate information exchange between relevant entities;

g) report regularly to the PAHO Governing Bodies on the progress made and challenges encountered in implementing the policy by submitting progress reports every five years.

Pan American Health Organization

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CSP30/11
Annex B

Report on the Financial and Administrative Implications of the Proposed Resolution for PASB

1. Agenda item: 4.6 - Policy to Strengthen National Regulatory Systems for Medicines and Other Health Technologies

2. Linkage to Program Budget of the Pan American Health Organization 2022-2023:

Outcome 8: Access to Health Technologies. Increased equitable access to essential medicines, vaccines, and other health technologies that are safe, affordable, clinically effective, cost-effective, and quality-assured, and rational use of medicines, with strengthened regulatory systems that contribute to achieving universal access to health and universal health coverage.

3. Financial implications:

a) Total estimated cost for implementation over the lifecycle of the resolution (including staff and activities):

This resolution does not have a lifecycle. Estimates were based on three years from the start of implementation (2023) until the end of the lifecycle of the PAHO Strategic Plan 2020-2025.

Areas	Estimated cost
Human resources	1,800,000
Training	300,000
Consultants/service contracts	1,200,000
Travel and meetings	900,000
Publications	215,000
Supplies and other expenses	115,000
Total	4,530,000

b) Estimated cost for the 2022-2023 biennium (including staff and activities):

Implementation of the resolution would begin once it is adopted. The corresponding estimated incremental costs would begin in 2023.

c) Of the estimated cost noted in *b)*, what can be subsumed under existing programmed activities?

Only incremental costs were calculated.

4. Administrative implications:

a) Indicate the levels of the Organization at which the work will be undertaken:

All levels of the Organization (country, subregional, and regional) will be involved. Active participation will also be needed from the ministries of health and subregional authorities of the Member States, as well as subregional organizations and mechanisms.

b) Additional staffing requirements (indicate additional required staff full-time equivalents, noting necessary skills profile):

One staff member will be needed to provide technical assistance to the Member States and support for working in a network on the coordination, formulation, implementation, and evaluation of regulatory systems (P4 or equivalent); and one staff member for technical assistance and support for regulatory strengthening activities (P2 or equivalent, 50%).

c) Time frames (indicate broad time frames for the implementation and evaluation):

Implementation of the policy will begin in 2023. A progress report will be submitted in 2027.

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Annex C

Analytical Form to Link Agenda Item with Organizational Mandates

1.	**Agenda item:** 4.6 - Policy to Strengthen National Regulatory Systems for Medicines and Other Health Technologies
2.	**Responsible unit:** Department of Health Systems and Services (HSS)/Medicines and Health Technologies Unit (HSS/MT)
3.	**Preparing officers:** Dr. James Fitzgerald and Dr. Analía Porrás
4.	**Link between Agenda item and the Sustainable Health Agenda for the Americas 2018-2030:** In the context of target 3.8 of the Sustainable Development Goals ("Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all"), the following goal of the Sustainable Health Agenda for the Americas 2018-2030 and several of its targets: *Goal 5:* Ensure access to essential medicines and vaccines, and to other priority health technologies, according to available scientific evidence and the national context. *Targets:* 5.1: Ensure timely access to medicines on the national essential medicines list, and to priority health technologies, without any payment at the point of care, service, or dispensing of the medicine, according to the national context (revised PAHO Strategic Plan outcome 4.3). 5.2: Reach 95% vaccination coverage70 in children under 5 years of age, through national vaccination programs (revised PAHO Strategic Plan outcome 1.5). 5.3: Have in place a national regulatory authority for medicines rated at level-3 capacity based on the WHO global benchmarking tool.71 (Adapted from PAHO Strategic Plan outcome 4.3). 5.4: Implement health technology assessment methodologies in the decision-making processes for incorporation in health systems72 (PAHO Report: Health Technology Assessment and Incorporation into Health Systems, Document CSP28/11 [2012]). 5.7: Strengthen national, subregional and regional mechanisms for negotiation and purchasing to improve the capacity of countries to obtain more affordable and equitable prices for medicines, vaccines, and other health technologies (Policy on Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies, PAHO Document CD55/10, Rev. 1 [2016]). 5.8: Taking into account public health perspectives, strengthen the capacity to implement intellectual property policies and health policies that promote research and development of medicines, vaccines and other health technologies for communicable and noncommunicable diseases that primarily affect developing countries and that promote access to affordable medicines, vaccines, and other health technologies (adapted from SDG target 3.b and Policy on Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies, PAHO Document CD55/10, Rev. 1 [2016]).

5. Link between Agenda item and the Strategic Plan of the Pan American Health Organization 2020-2025:

Outcome 8: Access to Health Technologies. Increased equitable access to essential medicines, vaccines, and other health technologies that are safe, affordable, clinically effective, cost-effective, and quality-assured, and rational use of medicines, with strengthened regulatory systems that contribute to achieving universal access to health and universal health coverage.

6. List of collaborating centers and national institutions linked to this Agenda item:

- Ministries of health, national health regulatory authorities, including institutions that are part of regulatory systems.
- Pan American Network for Drug Regulatory Harmonization and other international regulatory harmonization and convergence networks.
- Other government agencies and entities involved in developing and updating regulations; regulating; evaluating efficacy and safety; and surveillance, control, and inspection of health technologies.
- PAHO/WHO Collaborating Centers.
- Civil society and charitable organizations that promote strengthening of regulatory systems.
- Industrial associations linked to the development and manufacture of medicines and other health technologies.
- Universities, schools of health public, and other research and academic institutions.
- United Nations agencies.
- National and international development banks.
- Subregional agencies and integration mechanisms.

7. Best practices in this area and examples from countries within the Region of the Americas:

Some national regulatory authorities (NRAs) in the Region of the Americas have well-developed functions characteristic of a regulatory and enforcement agency, while others have significant challenges in terms of their structure, legal underpinnings, and processes for adequately performing these functions. Organizational and management structure, level of the development of the pharmaceutical sector, availability of trained human resources and financial resources, and existence of adequate infrastructure influence the performance of these functions.

After the adoption in 2010 of the system for strengthening regulatory capacities, it has been possible to facilitate the establishment of cooperation mechanisms between NRAs in the Region, allowing progress towards possible inter-institutional recognition with the consequent optimization of human and financial resources, through the implementation of practices in which the decisions of other jurisdictions are recognized.

The NRAs of Argentina, Brazil, Canada, Chile, Colombia, Cuba, Mexico, and the United States of America are recognized as regional RNAs of reference and, together with PAHO, have supported cooperation initiatives between countries by sharing good practices, developing guidelines to address common challenges, and supporting institutional development plans for other NRAs that are less strengthened, as well as leading harmonization and regulatory convergence initiatives at the regional and international levels.

There have been successful experiences in the Region in terms of advances in regulatory systems, in which cooperation between countries has been fundamental as part of the cooperation strategy. These include the establishment of new regulatory systems in Ecuador, El Salvador, Honduras, Nicaragua, and Paraguay, as well as the implementation of new subregional and multinational approaches that have improved regulatory capacities in countries with challenges inherent to small pharmaceutical markets. Examples include the Caribbean Regulatory System, based on the Caribbean Public Health Agency (CARPHA), and a mechanism for the joint evaluation of medicines that seeks to accelerate the availability of quality medicines, efficiency, and the best use of resources in the Central American subregion.

Through joint work in regional networks, focal points for specific health functions and technologies have developed successful approaches to sharing information and good regulatory practices, decision-making, and the development of joint projects. Examples include the Health Technology Assessment Network of the Americas (REdETSA), the network of pharmacovigilance focal points, and the network for prevention, detection, and response to substandard and falsified medical products.

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