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RESOLUTION

CSP30.R12

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

THE 30th PAN AMERICAN SANITARY CONFERENCE,

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

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;

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;

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;

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:

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

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.

(Seventh meeting, 29 September 2022)