30th PAN AMERICAN SANITARY CONFERENCE

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RESOLUTION

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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,

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

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