



PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION



50th DIRECTING COUNCIL

62nd SESSION OF THE REGIONAL COMMITTEE

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CD50.R9 (Eng.)
ORIGINAL: SPANISH

RESOLUTION

CD50.R9

STRENGTHENING NATIONAL REGULATORY AUTHORITIES FOR MEDICINES AND BIOLOGICALS

THE 50th DIRECTING COUNCIL,

Having reviewed the document *Strengthening National Regulatory Authorities for Medicines and Biologicals* (Document CD50/20);

Considering resolutions WHA45.17 (1992) and WHA47.17 (1994) of the 45th and 47th World Health Assemblies, respectively; document EB113.10 (2004) of the 113th Executive Board of the World Health Organization (WHO); document CD42/15 (2000) of the 42nd Directing Council of the Pan American Health Organization, on the essential public health functions and strengthening the steering role of the health authority at all levels of the State; and the Procedure for Designating Regulatory Authorities of Regional Reference for Medicines and Biologicals of the Pan American Health Organization;

Considering that strengthening the capacity of the national regulatory authorities and designating regulatory authorities of regional reference can lead to recognition of the existing capacity in the Region of the Americas and to the establishment of cooperation mechanisms that will make it possible to strengthen the steering role for other national regulatory authorities;

Recognizing the initiative of the Member States and PAHO/WHO in the preparation of a consensus-based instrument and the creation of a procedure for the qualification of regulatory authorities of regional reference;

Recognizing the possibility of having regulatory authorities of regional reference participate in product evaluation processes as part of the Pan American Health Organization's procurement mechanisms,

RESOLVES:

1. To urge the Member States to:
 - (a) strengthen and evaluate their regulatory capabilities with respect to the functions characteristic of a regulatory and oversight agency for medicines and biologicals, through an examination of the performance of their essential functions;
 - (b) use the results of the qualification activity and the designation of the regulatory authorities of regional reference to strengthen their performance in terms of the steering role of the health authority;
 - (c) support national regulatory authorities so they can benefit from the processes and information from national regulatory authorities of reference;
 - (d) promote the dissemination of information on the results and processes for the regulation and oversight of medicines, biologicals, and other health technologies;
 - (e) promote interaction and technical cooperation among countries;
 - (f) actively participate in the Pan American Network for Drug Regulatory Harmonization (PANDRH).
2. To request the Director to:
 - (a) support initiatives for the strengthening and qualification of national regulatory authorities to guarantee the quality, safety, and efficacy of medicines, biologicals, and other health technologies;
 - (b) widely disseminate in the countries of the Region of the Americas the available tools and procedures for qualification of the competencies of national regulatory authorities in medicines and biologicals and support development of the system for the qualification of national regulatory authorities and their designation as a regulatory authority of regional reference;

- (c) maintain and strengthen the collaboration of the Pan American Health Organization with the Member States in the area of medicines and biologicals regulation;
- (d) promote technical cooperation among country regulatory authorities as well as recognition of the existing capacity in the Region;
- (e) ensure that the Pan American Health Organization's procurement procedures for medicines and biologicals are supported by the existing capacity of the national regulatory authorities of reference to guarantee the quality, safety, and efficacy of these products.

(Seventh plenary, 30 September 2010)