Dissemination of Information. PAHO activities. November 2010

Dear **ECONMED** participants

As a follow up on **ECONMED** special focus on the 50º Directing Council of Pan American Health Organization and 62nd Session of the Regional Committee of World Health Organization for the Americas we are glad to share the working document Strengthening National Regulatory Authorities for Medicines and Biologicals (CD50/20, Rev. 1) –hyperlinked –note that the final version of the resolution will include some amendments- which was successfully submitted as a resolution yesterday at the council.

The document is important for a number of reasons not only for the region of the Americas but also at the global level, as it embodies PAHO member States will to strengthen the capacities of their national regulatory authorities to guarantee the quality, safety and efficacy of pharmaceutical products through authorization (or denial) of clinical trials and marketing approval for new products ,inspection and certification of manufacturers and distributors, post-marketing surveillance, and oversight of advertising and promotion of rational use of medicines .The recently approved resolution will help national authorities strengthen their regulatory systems in these and other key areas through self-assessments, the establishment of reference institutions, and sharing of information and experiences.

In approving the proposal, PAHO member States agreed to:

- **Strengthen and evaluate their own drug regulatory systems by assessing the performance of their essential functions, as defined by the World Health Organization (WHO).**
- **Use the process of qualification and designation of "*regulatory authorities of regional reference*" to strengthen their own systems' performance of essential regulatory functions.**
- **Promote dissemination of information on the results and processes of regulation and oversight of medicines, biologicals, and other health technologies.**
- **Actively participate in the Pan American Network for the Drug Regulatory Harmonization (PANDRH).**

The countries called on PAHO to support their efforts by:

- **Developing and implementing a process for evaluating the performance of national regulatory authorities in terms of the basic functions established by the World Health Organization (WHO).**
- **Creating mechanisms to provide technical training for national regulatory authorities.**
- **Promoting interaction and technical cooperation among countries.**