MAIN RESULTS of COLLABORATING CENTRE PAHO/WHO for the REGULATION of HEALTH TECHNOLOGIES (Medical Devices)

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2. Virtual course on regulation of medical devices

- ✓ the general objective of the virtual course is to strengthen professional competence of regulatory staff in the region
- ✓ this course will be given from September 19, 2016 through the virtual classroom CECMED. The architecture of the course has been built through lectures, literature, partial evaluations and discussion forums in each of the subjects taking the course a final evaluation
- ✓ course registration includes 38 participants from nine countries (Brazil, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Mexico, Panama and Paraguay)

1. Mapping of opportunities and needs for capacity building on regulation of medical devices in the region

- ✓ variables measured:
  - professional profile of regulatory staff
  - educational/ training needs and availability
  - staff development programs
  - training experiences and certification systems in the countries

- ✓ in this moment we are receiving replies from the countries

- ✓ the results of this survey must be processed to produce the report that will help to construct a regional folder for capacitation on medical devices regulation

3. Creation of a mirror group of IMDRF to establish a program to exchange adverse events reports among countries in the region

- ✓ implementation of the exchange program reporting of adverse events in the Region of the Americas (REDMA Program)
- ✓ technical meeting was held on 1srt and 2 June, in Havana, Cuba with the representatives of the regulatory authorities of the region: Argentina, Brazil, Colombia, El Salvador, Mexico, Panama, Dominican Republic, Uruguay, with support of PAHO officials
- ✓ there was consensus that future actions should be aimed at training to strengthen and implement effective vigilance systems in the region

4. Development of assessment indicators for the regulation of medical devices

- ✓ CC has worked together with PAHO in order to develop an appropriate system of indicators to assess Medical Device NRAs in the region
- ✓ regional tool with 7 modules and 104 indicators
- ✓ working together with WHO for a global assessment tool. Regional version reviewed
- ✓ new elements included in the regional version that have been put back to consideration of the countries

5. Technical document with the general requirements and procedure to evaluate marketing authorization applications for IVDMDs

- ✓ the proposed guideline has been designed upon the basis of GHTF and IMDRF recommendations
- ✓ a list of international standards and recommendations applicable to IVDMD and a procedure for the classification of these products have also been included
- ✓ it was addressed to NRAs in the region with poor development in the regulation of the IVDMDs.

NEXT STEPS

- to develop the portfolio of courses to strengthen the medical devices regulatory capacity in the region
- second edition of virtual course on regulation of medical devices
- strengthening surveillance systems for medical devices in the region (managing the program REDMA)
- to consolidate of assessment indicators for the regulation of medical devices