PAHO Update

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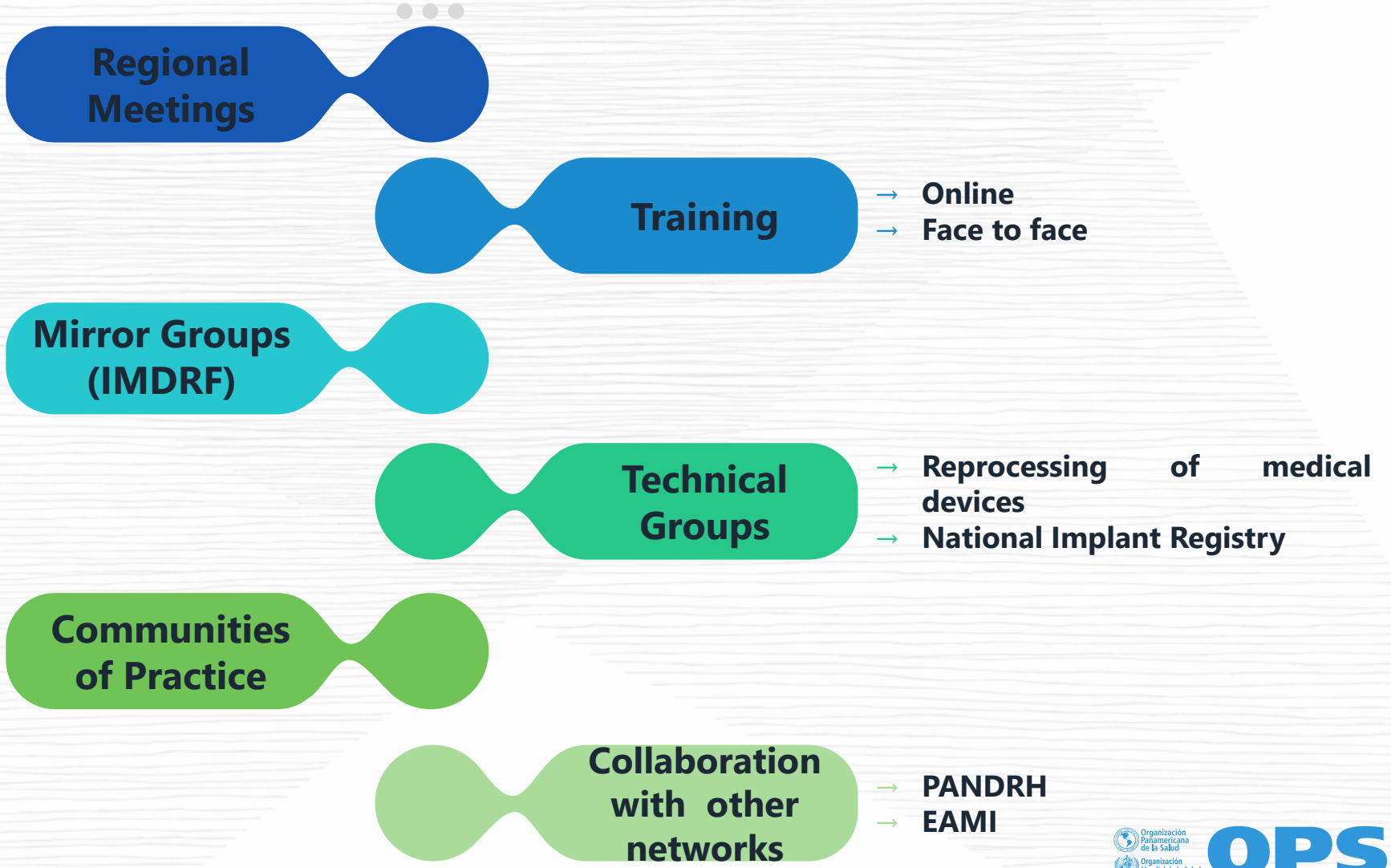
IMDRF Stakeholder Forum

Yekaterinburg | 17 September 2019

Pan American Health Organization
World Health Organization
Regional Office for the Americas

PAHO

OVERVIEW: ACTIVITIES OF THE REGIONAL WORKING GROUP



REGIONAL MEETINGS

	ARGENTINA		COLOMBIA		CANADA		COLOMBIA
2012	2013	2014	2015	2016	2017	2018	2019
CUBA		USA		BRAZIL MEXICO		EL SALVADOR	

9th REGIONAL MEETING
4 – 6 SEPTEMBER 2019 - BOGOTA, COLOMBIA

- Hosted by INVIMA (Colombia)
- Stakeholder session: **150 participants**
- Regulators session**:**

35 participants from **19 countries**

September 4th

Training session provided by FDA:

- IMDRF activities
- MDSAP Workshop

September 5th
Stakeholder session

- MDSAP
- Nomenclature
- Cybersecurity
- Personalized Medical Devices
- Good Regulatory Review Practices
- Standards

September 6th
Regulators session

- Advances and challenges at national level
- Collaboration with IMDRF
- Training activities
- Update on the activities of the Mirror Groups and Technical Groups
- Definition of the 2020 Work plan

OPS/OMS

ONLINE TRAINING

POSTMARKET SURVEILLANCE

- INVIMA-PAHO Collaboration
- **Spanish version:** two editions - 78 participants - *third edition began in June 2019*
- **English version:** July 2019, Caribbean countries
- 7 modules translated into English: *Technovigilance; London Protocol; Failure Mode and Effects Analysis; patient safety and clinical risk management; Reuse and reprocessing of medical devices; Signal generation; Intense surveillance and sentinel network*

IVD SURVEILLANCE

- INVIMA-PAHO Collaboration
- **Spanish version:** one edition - 36 participants from 15 countries

REGULATION OF MEDICAL DEVICES

- Developed by CECMED (Cuba), PAHO/WHO Collaborating Center
- **Spanish version:** two editions - 159 participants
- **English version:** Available in 2020

INTRODUCTION TO BIOMEDICAL TECHNOLOGY

- PAHO Virtual Campus for Public Health in collaboration with the University of Vermont
- **Spanish version:** one edition - 34 participants
- **English version:** one edition - 18 participants

HEALTH TECHNOLOGY PLANNING & MANAGEMENT

- PAHO Virtual Campus for Public Health in collaboration with the University of Vermont
- **Spanish version:** two editions - 107 participants. Third edition in September 2019.
- **English version:** two editions - 57 participants. Third edition in September 2019

ONLINE TRAINING

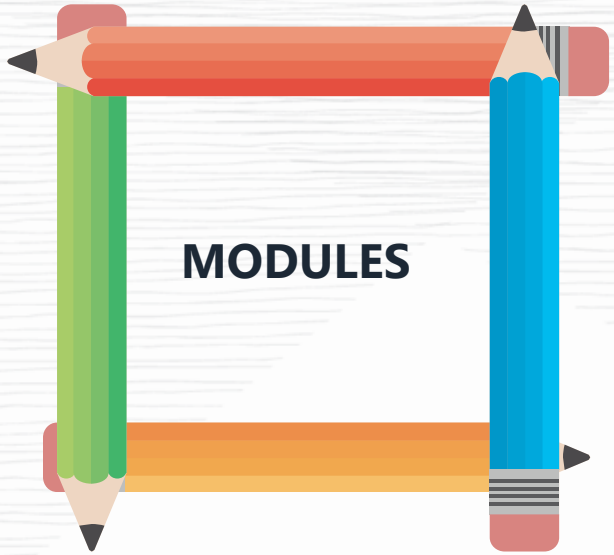
- **Medical Devices Regulation, with emphasis on postmarketing surveillance (English version)**
  - INVIMA-PAHO Collaboration
  - Nominations received from 11 countries: Jamaica, Saint Vincent and the Grenadines, Saint Lucia, Haiti, Bermuda, Grenada, Barbados, Trinidad and Tobago, Virgin Islands, Bahamas, Suriname
  - Participants: **35**
  - Start date: July 2019 | Duration: 5 months

POSTMARKET SURVEILLANCE SYSTEM (OVERVIEW)

Regulatory aspects and international overview of the postmarket surveillance systems in the Region of the Americas.

FAILURE MODES AND EFFECTS ANALYSIS (FMEA)

FMEA methodology for the analysis of clinical risks associated with the use of medical devices.



LONDON PROTOCOL

Fundamentals of London Protocol for the analysis of clinical risks associated with the use of medical devices.

PATIENT SAFETY & CLINICAL RISK MANAGEMENT

Phases, techniques, and tools currently used for an effective risk management process.

ONLINE TRAINING

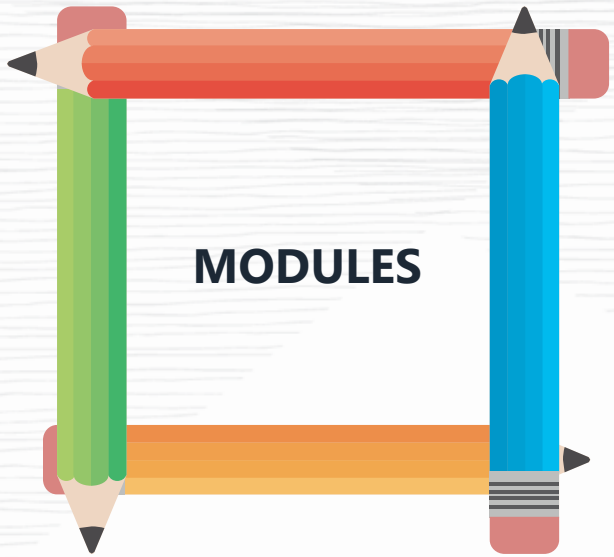
- **Regulation of medical devices, with emphasis on postmarketing surveillance (Spanish version)**
  - INVIMA-PAHO Collaboration
  - Nominations received from 14 countries: Chile, Nicaragua, Panama, El Salvador, Honduras, Venezuela, Peru, Guatemala, Costa Rica, Ecuador, Paraguay, Uruguay, Bolivia, Dominican Republic
  - Participants: **73**
  - Start date: June 2019 | Duration: 5 months

REGISTRATION

Technical and legal aspects required in the registration process within INVIMA and in accordance with the sanitary regulations in Colombia.

IVD SURVEILLANCE

Management guidelines, reporting tools, design and implementation of the IVD Vigilance Program.



TECHNOVIGILANCE

Componentes and functioning of the Technovigilance Program in Colombia.

PATIENT SAFETY AND RISK MANAGEMENT

Methodologies of risk manangement and continuous improvement.

FACE-TO-FACE TRAINING

Seminar "Medical Devices in Latin America: Collaboration between the EAMI (Ibero-American Regulators Network) and Regional Working Group for the Regulation of Medical Devices"

- In collaboration with the Spanish Agency of Medicines and Medical Devices (AEMPS), on behalf of the Ministry of Health, Consumer Affairs and Social Welfare and the Spanish Agency for International Development Cooperation (AECID)
- July 8-12 2019, Montevideo, Uruguay
- 27 participants from 17 countries benefited in the Region
- Focused on the principles of regulation of medical devices, clinical research, surveillance system, borderline products, personalized medical products, software as a medical device. As well as the REDMA Program, reuse, reprocessing and national registry of implantable products
- Establishment of agreements and commitments between the Secretariat of the EAMI Network and the Regional Working Group.

FACE-TO-FACE TRAINING

- **2nd Training on Medical Device Surveillance**
  - September 2-4 2019 in Bogota, Colombia
  - INVIMA-PAHO collaboration
  - Representatives from 15 regulatory authorities of the Region (best results in the online course)

- **1st Training on Medical Device Surveillance**
  - Part of the project “Strengthening the regulatory capabilities of medical devices in the Region of the Americas”, the first project of the PANDRH Network focused on medical devices
  - First edition held in 2017
  - Representatives from 9 regulatory authorities (best results in the online course)

COLLABORATION WITH IMDRF

- Participation in the IMDRF Working Groups
  - Medical Device Clinical Evaluation (ANMAT, Argentina)
  - Personalized Medical Devices (ANMAT, Argentina)
  - Good Regulatory Review Practices (INVIMA, Colombia)
  - Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (ANMAT – Argentina, CECMED – Cuba, Ministry of Health of Uruguay)

- Creation of one new Mirror Working Group on *Good Regulatory Review Practices*

IMDRF MIRROR WORKING GROUPS

- New Mirror Working Group created in the last Regional Meeting (September, 2019)

NCAR Exchange Program: REDMA Program	Good Regulatory Review Practices	Personalized medical devices	Adverse Event Terminology
CECMED, CUBA	INVIMA, COLOMBIA	ANMAT, ARGENTINA	MINISTRY OF HEALTH, URUGUAY

REDMA Program

OBJECTIVES

→ Exchange reports of adverse events of Medical Devices among NRA members of the Regional Group

→ Promote the development of surveillance systems

2014

Establishment of the Mirror Working Group

Secretariat:

- CECMED
- ANVISA
- INVIMA

2015 → 2017

Baseline documents prepared & approved

- Criterios y Formularios
- Declaración de Conformidad
- Funcionamiento de la Secretaría
- Manual de Usuario del Sistema Web REDMA

2016

Technical Meeting for the implementation of the REDMA Program in Havana

2017

REDMA Web System

PILOT STUDY
ARG, BRA, CHI, COL, CUB, MEX, ELS, PAN, DOR, URU.

12 Reports:
9 confidential & 3 Public

2018

Technical Meeting for the REDMA Program in Havana

2019

Integration of the **REDMA Web Sy**stem within **PRAIS**

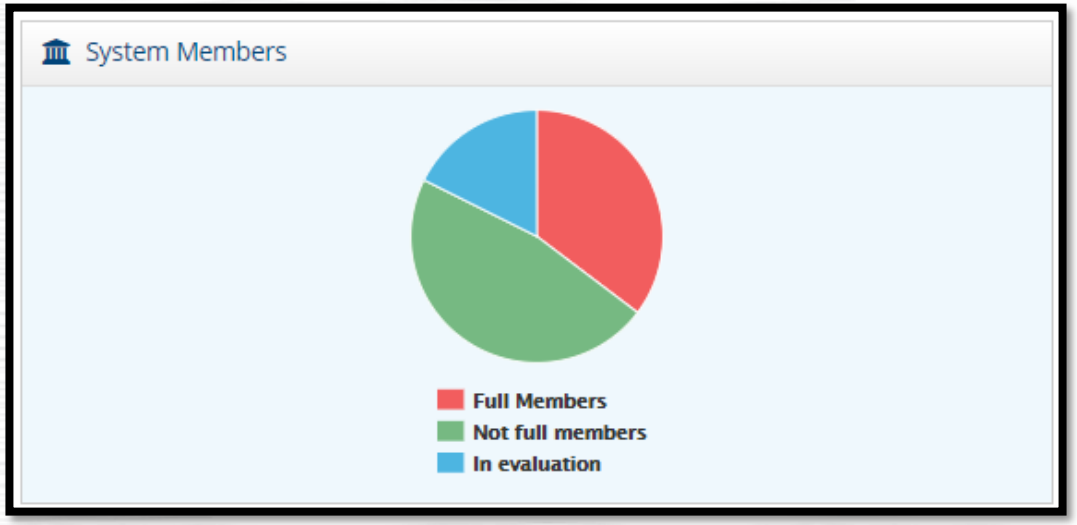
Full implementation in March

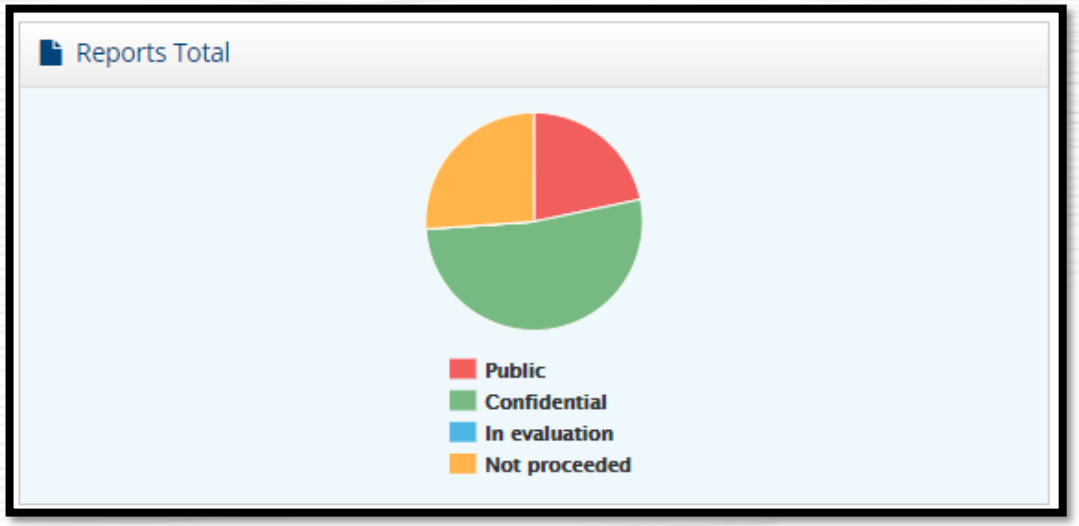
CoP REDMA Program

- 44 members

REDMA Program

- **7** Associate Members
  - Bolivia, Ecuador (Ministry of Health), Paraguay, El Salvador, Uruguay, Panama, Dominican Republic
- **6** Full Members
  - Argentina, Brazil, Colombia, Cuba, Chile, Mexico
- Completing the registration process:
  - 2 countries: Ecuador (ARCSA) and Honduras





- Total number of Reports: **17**
  - **12** confidential
  - **5** non-confidential

MIRROR GROUP: TERMINOLOGY OF ADVERSE EVENTS

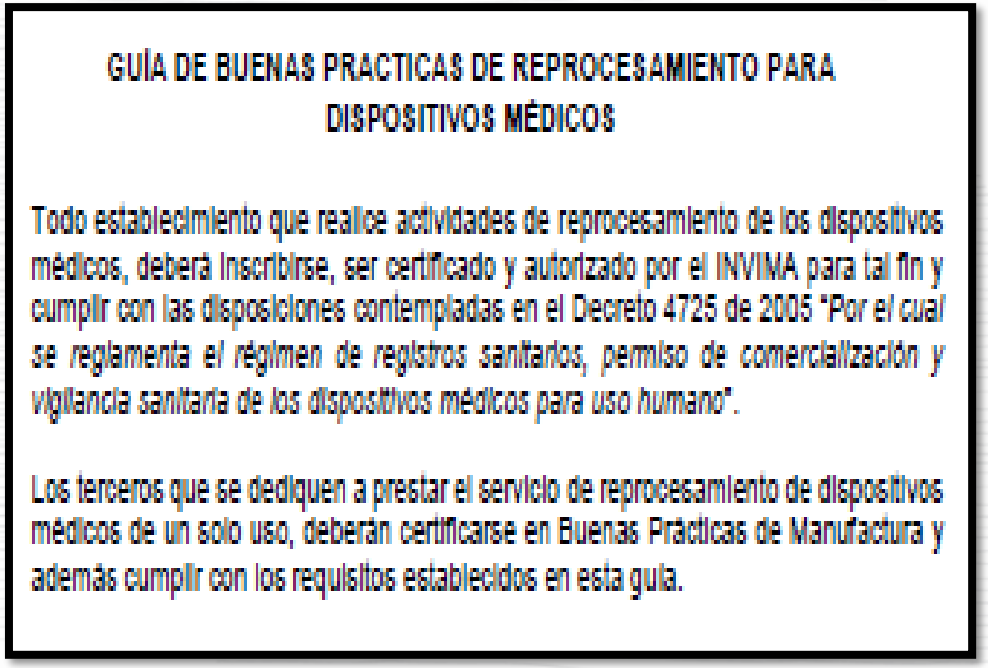
- Created during the 8th Regional Meeting in El Salvador and coordinated by Uruguay (Ministry of Health).

- Analysis of the *IMDRF document "IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes"*

- Translation into Spanish of the following annexes:
  - *Annex A: Medical Device Problem Terms and Codes*
  - *Annex B: Cause Investigation – type of investigation terms and codes*
  - *Annex C: Cause Investigation – investigation findings terms and codes*
  - *Annex D: Cause Investigation – investigation conclusion terms and codes*

TECHNICAL GROUP: REPROCESSING OF MEDICAL DEVICES

- Coordinated by INVIMA, Colombia
- Mapping on the situation of reuse and reprocessing of medical devices in the Region
- Preparation of the document “Guide to good reprocessing practices of medical devices” by INVIMA, which is in the process of validation by the members of the Regional Working Group



GUÍA DE BUENAS PRACTICAS DE REPROCESAMIENTO PARA DISPOSITIVOS MÉDICOS

Todo establecimiento que realice actividades de reprocesamiento de los dispositivos médicos, deberá inscribirse, ser certificado y autorizado por el INVIMA para tal fin y cumplir con las disposiciones contempladas en el Decreto 4725 de 2005 "*Por el cual se reglamenta el régimen de registros sanitarios, permiso de comercialización y vigilancia sanitaria de los dispositivos médicos para uso humano*".

Los terceros que se dediquen a prestar el servicio de reprocesamiento de dispositivos médicos de un solo uso, deberán certificarse en Buenas Prácticas de Manufactura y además cumplir con los requisitos establecidos en esta guía.

TECHNICAL GROUP: REGISTRY OF IMPLANTS

- Created during the 8th Regional Meeting in El Salvador and coordinated by ANVISA.

- ANVISA prepared the questionnaire *National Implant Registry* with the objective of identifying which countries have implant registries and to get information about the models adopted in order to elaborate an analysis of the situation in the Region of the Americas. The survey was translated from Portuguese into Spanish and English.
  - Shared with the Regional Working Group in July 2019 for feedback.

COLLABORATION WITH MDSAP

- Training provided by FDA (September 2019, Colombia) as part of the Annual Regional Meeting
- MDSAP Meeting will be held at PAHO HQ in the first week of December, and there will be an Open Forum for sharing information about MDSAP on 5-6 December (RSVP: Anita Epps, from FDA: Anita.Epps@fda.hhs.gov)
- Project on exchange of GMP Certifications, coordinated by ANVISA
  - A survey adapted from MDSAP documents were sent to Argentina, Chile, Colombia, Cuba and Mexico, with the goal of mapping current practices and identifying possible gaps and areas for improvement
  - The questions in the survey were divided into 7 modules:
    - Management
    - Device marketing authorization and registration of facilities
    - Measurement, analysis and improvements
    - Adverse events of medical devices and advisory notices
    - Design and development
    - Production and service controls
    - Purchases
  - A report was prepared based on the information received from the countries
  - Next step is to develop training activities, considering the recent decision from MDSAP on creating the category of affiliate member (first activity will be a webinar by ANVISA on 26 September)

THANK YOU!