NATIONAL ADMINISTRATION OF DRUGS, FOOD AND MEDICAL DEVICES

Directorate of Evaluation and Research of Non-Classified / Innovative MD

Dra. Marcela Rizzo
ANMAT

- Decentralized Agency under the National Public Administration
- Created in 1992
- Nationwide jurisdiction
ANMAT Objective

To ensure that medicines, foodstuff and medical devices available to the public are efficacious, safe and of the required quality.
ANMAT

- National Directorate of Medical Devices
- Surveillance of health products
- National Institute of Drugs
- Evaluation of technology
- National Institute of Food
INAME
National Institute of Drugs

Controls and monitors the safety and quality of drugs, Chemical products and pharmaceutical forms of medicines.
INAL

National Institute of Food

Controls and monitors the safety and quality of supplies such as additives, colorants, sweeteners and ingredients used in human food.
MD
National Directorate of Medical Devices
Controls and monitors the quality, safety and efficacy of the equipment and devices used in human medicine, dentistry and biochemistry.
VIGILANCE SYSTEMS

TECHNO VIGILANCE

FOOD VIGILANCE

PHARMACO VIGILANCE
Products regulated by ANMAT

- Medicines.
- Foodstuff.
- Medical devices.
- Cosmetics, Toiletries and hygiene products.
- Household cleaning products.
- Diagnostic reagents.
- Dietary supplements.
INTERNATIONAL AFFAIRS

✓ MERCOSUR: all legislation are harmonized.

✓ First National Drug Regulatory Agency designated as Reference Authority by PAHO.

✓ ANMAT was vice-chair with FDA, in the meeting of the Member State Mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products (November 2013 - Geneva)
Argentina was chosen to:

- Represent the region
- Represent PAHO
- And complying with all procedural requirements requested by IMDRF to be Member
A.N.M.A.T is representing PAHO and participating in two working groups:

- Personalized Medical Devices.
- Clinical Trials
Regional Working Group on Medical Device Regulation

- Established: July, 2012 with 12 member countries; currently with 20.

- Objective: To Strengthen the Regulatory capacity for Medical Devices in the Region of the Americas.

Mirrow Working Group for the NCAR Exchange Program:

REDMA.

- Secretariat: CECMED (Cuba), INVIMA (Colombia) and ANVISA (Brasil)

- Operation and procedures documents of the REDMA Program, based on IMDRF.

- Software developed by CECMED for the secure exchange of adverse events reports (REDMA Web System)

- Full implementation in 2018
INTERNATIONAL AFFAIRS

✓ IX CPARF. San Salvador, El Salvador. 24 -26 October

ARGENTINA (Conferences)

- Personalized Medical Devices
- Software as a Medical Device
STRENGTHENING SUCH AS REFERENCE REGULATOR AUTHORITY

Past
Regulation and Control

Present - Future
Health Surveillance
New Vision
Regulatory Science
Health Surveillance based on Regulatory Science

- Scientific Support
- Technical Capacity
- Decisions based on scientific and technical knowledge
Tango Argentino
Thank you

谢谢
Gracias

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