

NATIONAL ADMINISTRATION OF DRUGS, FOOD AND MEDICAL DEVICES

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

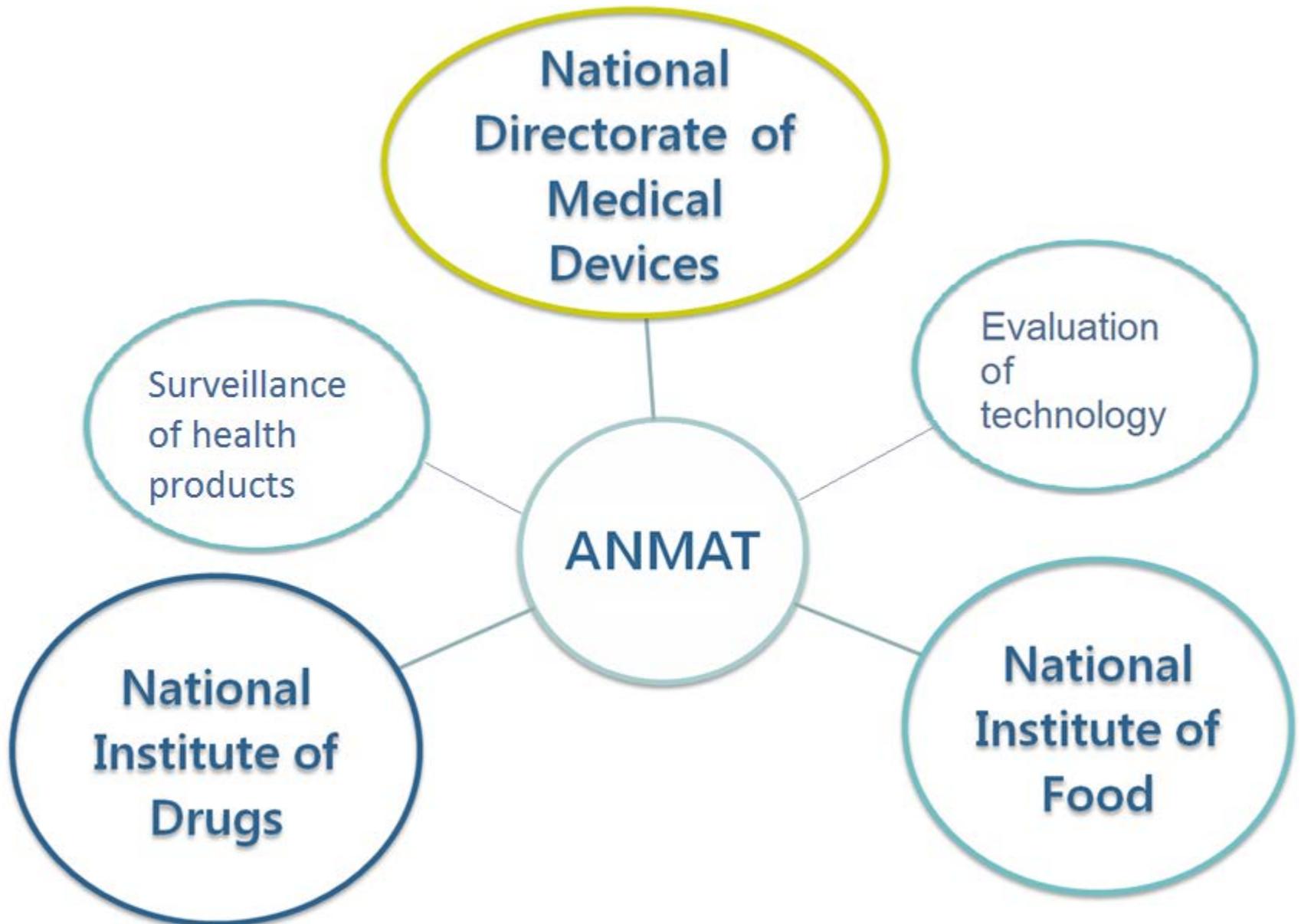
Dra. Marcela Rizzo

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



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/false-labelled/falsified/counterfeit (SSFFC) medical products (November 2013 - Geneva)**



**Pan American
Health
Organization**



**World Health
Organization**

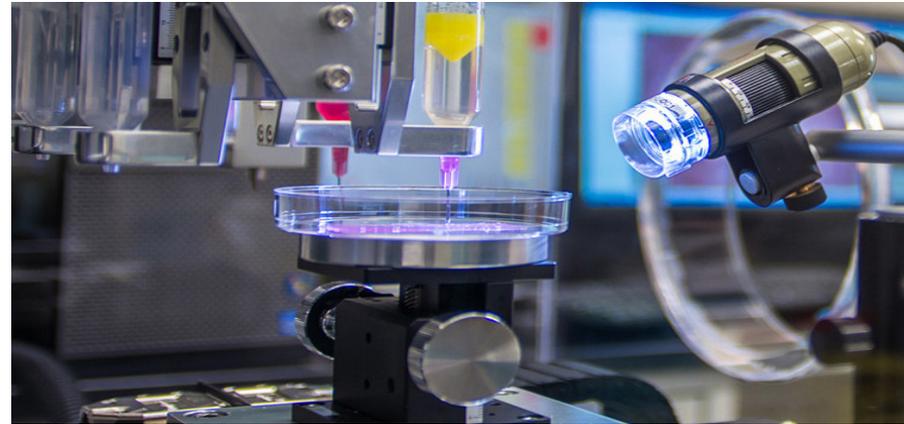
Argentina was chosen to:

- **Represent the region**
- **Represent PAHO**
- **And complying with all procedural requirements requested by IMDRF to be Member**

INTERNATIONAL AFFAIRS

A.N.M.A.T is representing PAHO and participating in two working groups:

- ✓ **Personalized Medical Devices.**
- ✓ **Clinical Trials**





**Pan American
Health
Organization**



**World Health
Organization**



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.**
- ✓ **Argentina – Bolivia – Brazil – Canada – Chile – Colombia – Costa Rica – Cuba – Dominican Republic – Ecuador – El Salvador – Honduras – Jamaica – Mexico – Nicaragua – Panama – Paraguay – Peru – Trinidad & Tobago – Uruguay**



Pan American
Health
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Mirror 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



Health Surveillance
based on
Regulatory Science

Scientific Support

Technical Capacity

Decisions based on
scientific and
technical
knowledge







Tangó

Argentino





Thank you
謝謝
Gracias



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