anmat
Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

ANMAT's experience as an affiliate member of MDSAP

June 17th, 2021

About ANMAT

The **National Administration of Drugs, Food and Medical Technology (ANMAT, for its acronym in Spanish)**, created in 1992, is the regulatory agency responsible for registering, controlling, oversight and monitoring health products produced, distributed and marketed in the Republic of Argentina.

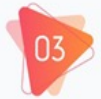
5 **venues**

1085 agents

Strategic targets

Strengthen ANMAT’s role as a High Surveillance Agency for Health

Optimizing tools to ensure product safety



Accelerate assessment processes for secure access to new products and technologies

Continue with the processes of technological innovation

NATIONAL DRUGS INSTITUTE (INAME, for its acronym in Spanish)

Controls and oversees the safety, quality and effectiveness of medicines (synthetic and biological) and the pharmaceutical active ingredients.

NATIONAL FOOD INSTITUTE (INAL, for its acronym in Spanish)

Controls and oversees the safety, quality and effectiveness of food.

NATIONAL INSTITUTE OF MEDICAL PRODUCTS (INPM, for its acronym in Spanish)

Controls and oversees the safety, quality and effectiveness of medical products and IVD products, used in human medicine.

Organizational Structure

ANMAT in International scenarios

- Scheme of Cooperation in Pharmaceutical Inspections – PIC/S
  Participant Authority

- International Council for the Harmonization of Technical Requirements for Pharmaceuticals for Human Use - ICH
  Observer

- International Program of Pharmaceutical Regulators – IPRP
  Member

- International Coalition of Drug Regulatory Agencies – ICMRA
  Observer

ANMAT in International scenarios

- PAHO/WHO
  Member

  Regulatory Authorities of Regional Reference – NRAs – Level IV
  ANMAT' coordination for two years (2019 -2021)

  Regional Working Group on Medical Devices Regulation
  Member

  PARF network
  Member

ANMAT in International scenarios

Argentina is a member of MERCOSUR, and therefore participates in the elaboration of various technical regulations, proposing, drafting and/or commenting on issues of interest to the country and the region.

ANMAT in International scenarios

ANMAT participates in COPROSAL (Health Products Commission) in Sub-Working Group No. 11 (Health)

Working Groups

- Working Group on Good Practices in the Pharmaceutical Area
- Clinical Research Working Group
- Cosmetics Subcommission
- Household Cleaners Subcommission
- Medical Products Subcommission
- Psychotropic and Narcotic Drugs Subcommission

ANMAT in International scenarios

The International Medical Devices Regulators Forum aims to accelerate international regulatory harmonization and convergence of medical devices.

ANMAT participates in the following working groups:

- Clinical Evaluation of Medical Products
- Personalized Medical Products
- Principles of Classification of Medical Products for In Vitro Diagnostics

ANMAT in International scenarios

The International Medical Device Regulators Forum (IMDRF) recognizes a global approach to auditing and monitoring the manufacture of medical devices. The **Medical Devices Single Audit Program (MDSAP)** allows an MDSAP-recognized Audit Organization to conduct a single audit of a medical device manufacturer that meets the relevant requirements of regulatory audits participating in the program.

How was the road to MDSAP?

- ANMAT noted the MDSAP for its participation in the IMDRF.
- In accordance with the Terms of Reference, the membership application was made by **completing the MDSAP F0035.001 Affiliate Members Application Form**.
- A **comparative table of similarities** was made between ISO 13485:2016 and ANMAT 3266/13.
- Guides adopted from IMDRF and GHTF were described.
- The "online" trainings established by MDSAP were carried out.
- **Affiliate Member** since January 2020.

What do we offer to the MDSAP?

- Technical transfer to countries of the region
- Experience and knowledge in the regulatory area of Medical Devices, reflected in different international spaces:

  Regional Group for Regulation of Medical Devices of the Americas of the Pan American Health Organization (PAHO/WHO): Workstreams

  MERCOSUR – SWG 11 – Medical Products Subcommission

MDSAP Benefits

- Sovereignty of the Regulatory Authority **to decide how to use** the MDSAP Audit results.
- Resources **optimization** for conducting audits around the world.
- Implementation of **reliance** between health authorities.
- **Reducing** the burden on economic and human resources for the manufacturer.
- Implementation of **common** audit **criteria**.

MDSAP Benefits

- Contribution of a **standardized** rating system.
- **Absence of restrictions** on the geographical location of the manufacturer.
- Information and update of the Auditinging Organizations.
- Interact and identify which Authorities apply ISO 13485
- Rethinking the inspection scheme.

National Regulatory Framework

In-country inspections:

- Inspections to Manufacturing and Importing companies of Medical Products. ANMAT 3266/13. Mercosur Resolution GMC 20/11
- Inspections to companies Distributing Medical Products. ANMAT 6052/13

National Regulatory Framework

Overseas inspections:

- Countries with regulations similar to its own, inspections are not carried out by ANMAT
- MERCOSUR Member Countries are recognized in accordance with MERCOSUR Resolution 20/17
- Other countries are subject to inspections by ANMAT under Order 3266/13.

Pandemic Context

- Due to the pandemic that hit us in 2020, decisions had to be made regarding companies based abroad that commercialize MEDICAL PRODUCTS in our country. https://www.argentina.gob.ar/noticias/verificacion-de-buenas-practicas-de-fabricacion-de-plantas-en-paises-extranjeros-para

- We have received and analyzed 3 ISO 13485 certificates from companies based abroad that have a company in Argentina that want to import their products.

- Currently, 1 MDSAP certificate from a foreign-based company has been received and analyzed.

Pandemic Context

Meeting with stakeholders

In order to strengthen the export performance of the MDSAP, we have informed various **Government Agencies** and **Sectoral Chambers** of the potential benefits of participating in the scheme.

- *Workshop on Export Supply,* within the **Commercial Intelligence** area of the *Ministry of Foreign Affairs, Foreign Trade and Worship*, together with the *Ministry of Productive Development* and the *Investment Agency*, support the national industry to increase its export capacity. ANMAT is actively involved in providing the regulated sector with an up-to-date regulatory framework.

Challenges

- ✓ Cooperate in the processes of interest and involvement of the Program with other countries of the region.
- ✓ Promote participation in regulatory convergence and harmonization scenarios in a sustainable, strategic and efficient way.
- ✓ Participate in continuous training in MDSAP to share tangible results, in the medium and long term, provided by the membership in the Program.

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Ministerio de Salud
Argentina

Thank you!