Regulatory Updates from IMDRF Management Committee and Official Observers

IMDRF 22° Management Committee Meeting
Sydney, September 2022

About Us

The **National Administration of Drugs, Food and Medical Devices** (ANMAT), created in 1992, is the regulatory authority responsible for registering, controlling and surveilling health products manufactured, distributed and marketed in the Republic of Argentina.

30 AÑOS anmat

Ministerio de Salud
Argentina

1

National Regulatory Authority with capacities and resources based on Regulatory Science.

2

Regulatory framework adapted to international regulatory convergence and coherence criteria.

3

Active involvement in the international arena, with participation in several WGs from different fields.

4

Being a part of the convergence and harmonization processes within the international framework.

ANMAT in the International Arena

- ✓ Pharmaceutical Inspection Cooperation Scheme – 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
- ✓ National Regulatory Authority (NRA) for medicines in the Americas, Regional Reference Authorities in the Americas (AMRO/PAHO)

ANMAT in the International Arena

PAHO/WHO

Regulatory Authorities for the Strengthening of the Regulatory Capacity of Medical Devices in the Americas – since 2012 - Regional Working Group on Medical Device Regulation, in which 25 countries from the Americas currently participate.

Member of “REDMA Program” (NCAR)

ANMAT in the International Arena

MERCOSUR

The Southern Cone Common Market is a regional integration process, initially established by Argentina, Brazil, Paraguay and Uruguay.

Working on regulatory harmonization of Medical Devices in Sub-Working Group No. 11 (SG11-Health)

ANMAT in the International Arena

MDSAP

Affiliate Member since January 2020

The first MDSAP certificate from a foreign-based company was received and analyzed.

Administrative time was reduced and resources were optimized in the certification process of Medical Devices Good Manufacturing Practices.

ANMAT in the International Arena

Since 2012, ANMAT has participated in IMDRF meetings as an invited guest via PAHO.

Since then, it has participated in the following working groups:

- ✓ Medical Device Clinical Evaluation
- ✓ Personalized Medical Devices
- ✓ Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

ANMAT in the International Arena

Since August 2021 ANMAT has been an Official Observer to the IMDRF and this has allowed for increased participation in different working groups:

- ✓ Artificial Intelligence Medical Devices (AIMD)
- ✓ Medical Device Cybersecurity Guide
- ✓ Clinical Evidence of Medical Products for IVD
- ✓ Good Regulatory Review Practices
- ✓ Software as Medical Devices

How we implement the IMDRF documents

Different ways to internalize IMDRF documents:

- ✓ **MECOSUR Technical Regulations:** If the subject is in the interest of the regional group.
- ✓ **Resolution/Regulation:** ANMAT is an autarchic agency with the power of issuing its own regulations within the sphere of its competence.
- ✓ **Guidelines:** If the document to be internalized pursues purposes similar to the existing regulations and some specific clarification is required for any reason, a guide is developed.

How we implement the IMDRF documents

Final Draft Guide:

- ✓ The guideline for SaMD and AIMD: focuses on the requirements for premarket approval and application of Quality Management System

- ✓ The guideline for Personalized Medical Devices

First Argentine AIM
currently approved

How we implement the IMDRF documents

IMDRF

- Principles of In Vitro Diagnostic (IVD) Medical Devices Classification - IMDRF/IVD WG/N64FINAL:2021

MERCOSUR

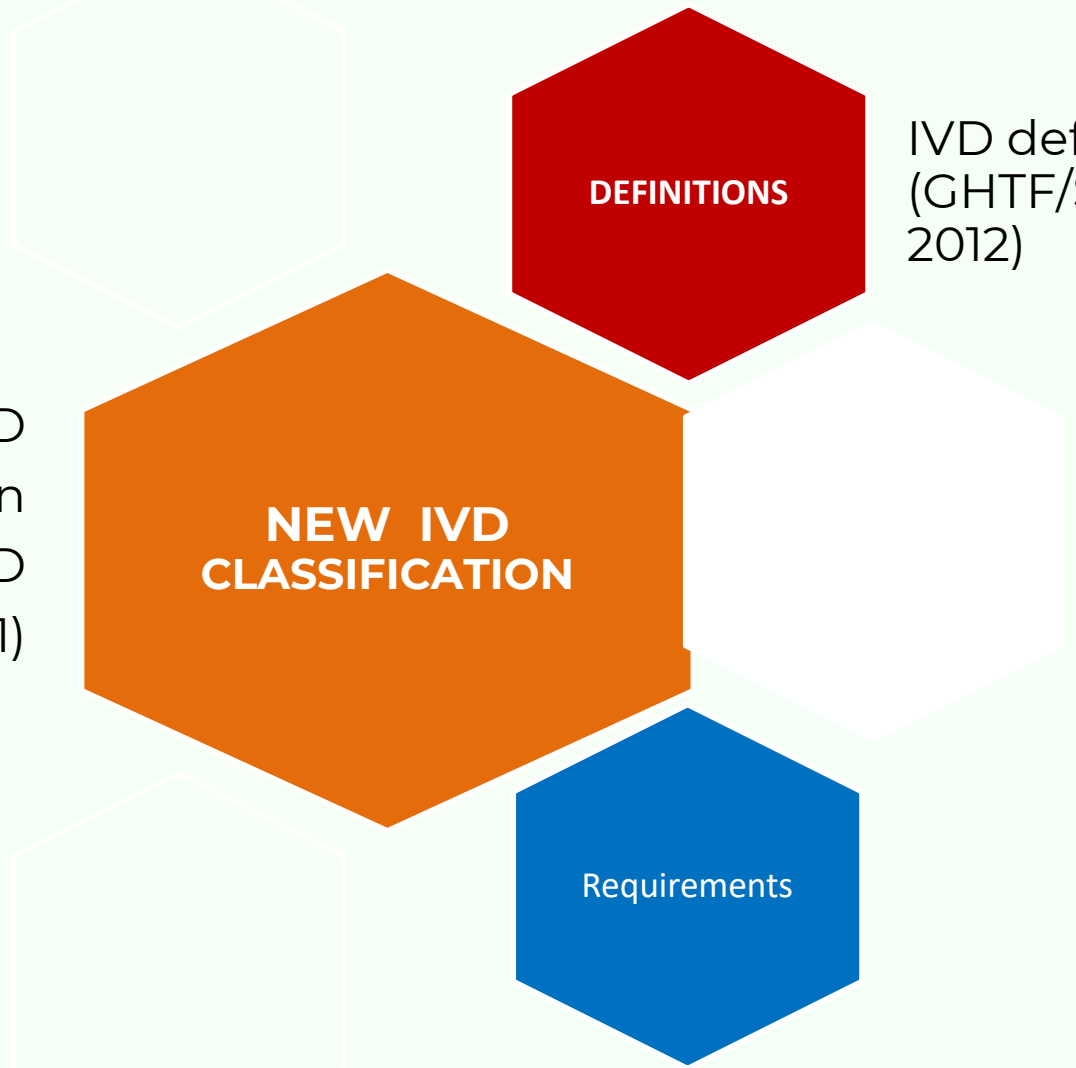
- GMC Resolution No. 24/2021: "Technical Regulation for the Registration of In Vitro Diagnostic Medical Device "

ANMAT

- ANMAT Regulation 2198/2022 Update of Regulation for In Vitro Diagnostic Medical Device

ANMAT Regulation 2198/22

Principles IVD Classification (IMDRF/IVD WG/N64FINAL:2021)



IVD definition (GHTF/SG1/N071 2012)

Challenges

ANMAT intends to continue joining regulatory convergence and harmonization processes that represent IMDRF foundational objectives and, also, **to make contributions to the IMDRF** at large and to **its valuable Working Items**

Thank you!

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