



Regulatory Update for ANMAT

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IMDRF International Medical Device
Regulators Forum

Good Post-market Surveillance Practices

DI-2023-8194-APN-ANMAT#MS: This document provides guidance on the post-market surveillance process to be conducted by medical devices manufacturers and importers. It updates some concepts and establishes new deadlines and notification criteria.

Good Post-market Surveillance Practices



Based on:

IMDRF/AE WG/N43 - IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes

ISO/TR 20416:2020 - Post-market surveillance for manufacturers



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ARGOS: Post-market Surveillance System

Stakeholders

The screenshot displays the ARGOS web application interface. At the top, the logo for 'anmat' (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica) is visible, along with the text 'PM_regulados v1.0.0.0'. The page title is 'A.N.M.A.T. - Administración Nacional de Medicamentos, Alimentos y Tecnología Médica'. Below the header, there are navigation links: 'Razón Social', 'Mis Trámites', 'Ayuda', and 'Salir'. The main content area is titled 'Seleccione el trámite' and contains a form with the following elements:

- Trámite a realizar:** Radio buttons for 'Evento adverso' and 'Acción de campo' (selected).
- Modalidad:** Radio buttons for 'Retiro de Mercado' and 'Modificación de producto'.
- Ingrese su email:** A text input field with a placeholder 'Ingrese su email' and a search icon.
- ADVERTENCIA:** A red-bordered box containing the text: 'El trámite en Estado Borrador se encuentra en confección y aún no es válido como expediente en curso hasta tanto no complete todos los requisitos y pase al estado Enviado.'
- Buttons:** 'Generar trámite' (grey) and 'Completar trámite cargado' (blue).

At the bottom of the page, there is a footer with the text 'ACES SA, 30708684305' and 'PM_regulados v1.0.0.0'. A notification badge in the bottom right corner indicates '12 nuevas notificaciones'.

Pilot project: Initial testing of Argos System

Stakeholders chambers	Participants
CADIEM - Argentine Chamber of Distributors and Importers of Medical Equipment	5
CADIT - Chamber of Traumatology Industry	2
CAPRODI - Argentine Chamber of Diagnostic Reagents	5
CAFIME - Argentine Chamber of Medical Implant Manufacturers	3
CADIME - Chamber of Medical Diagnostic Institutions	1
CADIPO - Argentine Chamber of Distributors and Importers of Medical Devices and Orthopedic Products	1
UAPE - Argentine Union of State Suppliers	3
CAEHFA - Chamber of Hospital Equipment Manufactured in Argentina	1
Total:	20

Training to Stakeholders

→ **Face-to-face training**



→ **Online course** (ANMAT Virtual Campus)

→ **External events**
(Congress, Conference, Exhibition)

ANMAT Federal meetings
ExpoMedical 2023
CACI: College of Interventional Cardioangiologists
CACID - Chamber of Commerce and Dental Industry

MAIN OBJECTIVES:

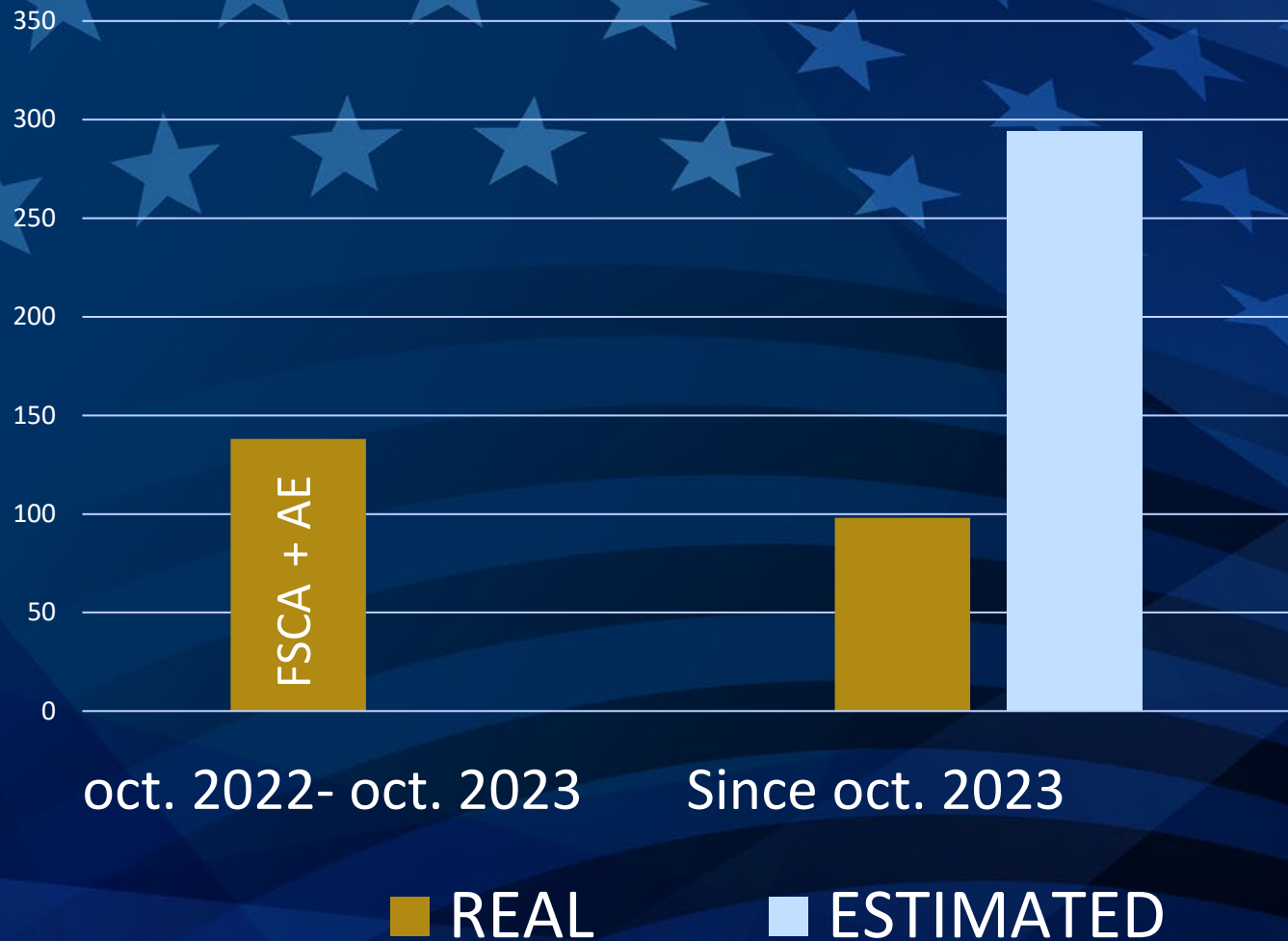
- **New deadlines and notification criteria.**
- **Implementation of a new IT system.**
- **Database available**

ACHIEVEMENTS:

- **Optimize communication channels.**
- **Reduce evaluation times.**
- **Data Analysis: analytics tools to classify reports into categories**

Number of reports

Total = FSCA + AE



ARGOS: "Public Library"

- Public access to view the reports (only FSCA) with the corresponding FSN and its status (In Process or Closed)
- In "Closed" notification shows the Final Report.

anmat
Administración Nacional de Medicamentos, Alimentos y Tecnología Médica
PM_regulados v1.0.0.0

A.N.M.A.T. - Administración Nacional de Medicamentos, Alimentos y Tecnología Médica
Ministerio de Salud
Presidencia de la Nación

Mis evaluaciones Distribuidor Usuarios Administrador Firma Observados Biblioteca Salir

Filtros de búsqueda para la biblioteca

Razón Social: PM N°:

Trámites encontrados : 44 registros.

ID	Razón Social	Tipo de Trámite	Modalidad	PM N°	Tipo de Producto	Marca	Modelo	Lote	Estado	Documento FSN	Informe Cierre
44		Acción correctiva de seguridad en campo	Modificación de producto						En proceso	<input type="button" value="Ver..."/>	<input type="button" value="Ver..."/>
47		Acción	Modificación						En	<input type="button" value="Ver..."/>	<input type="button" value="Ver..."/>

Post-Marketing Monitoring Plan

Product: ELISA test for determination of IgG/IgM antibodies to anti *Trypanosoma cruzi* in human serum/plasma.

Objective: Comparative evaluation of ELISA test for the detection of specific antibodies against *Trypanosoma cruzi* in serum/plasma, to verify specificity and sensitivity of the IVD available in the national market.

Post-Marketing Monitoring Plan

We requested 3 kits (x192 tests) from 10 companies with marketed products.

The study is carried out by the Reference Center for Research and Diagnosis of Chagas Disease INP "Dr. "Fatala Chaben".

Current status: two brands were evaluated (6 kits) and 5 remain (15 kits). The trials are expected to be completed in March.

Guideline for SaMD and AIMD

The guideline focuses on the requirements for pre-market approval and application of Quality Management System

- Public Consultation: November-December 2023.
- Current Status: Analysis of comments

Based on:

IMDRF/SaMD WG/N23 Software as a Medical Device (SaMD): Application of Quality Management System

IMDRF/AIMD WG/N67 Machine Learning-enabled Medical Devices: Key Terms and Definitions

IMDRF/SaMD WG/N10 Software as a Medical Device (SaMD): Key Definitions



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United States
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