IMDRF International Medical Device Regulators Forum

Regulatory Updates

(Saudi Food & Drug Authority)

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Overview

- ❑ Medical Devices strategical objectives
- ❑ UDI Compliance Timeframe
- ❑ Post-market Surveillance
- ❑ Clinical Trials of medical devices
- ❑ Marketing Authorization Statistics MDMA
- ❑ National Diagnostic Reference Levels (NDRLs)
- ❑ Guidance Under Development
- ❑ News on international activities

Medical Devices Strategical Objectives

- Support **Research and Innovation** (Pathways for innovators and Clinical Trials).
- **Enhancing** requirements of new technology and bio-tech products to be align an updated with all international requirement
- **Strengthen** international collaboration with IMDRF, ISO, IEC, WHO, GHWP…
- **Improving Communication** and Awareness with Health Care Providers and Public

Strategical Objectives (Cont'd)

1. Support Research and Innovation

- **Recently MD Innovation approved:**
  - ✓ Dental surgical tools
  - ✓ In-vitro diagnostic MD that utilize biotechnology to accurately detect concentrations of **antipsychotic** medications in the blood.
  - ✓ Suture Needle Retaining Strap
  - ✓ Thermal imaging analysis software
- **Updated** SFDA-MD Guidance:
  - ✓ Guidance on Manufacturing Paths of Medical Devices (MDS – G011)
  - ✓ Guidance on Innovative Medical Devices (MDS – G002)

Strategical Objectives (Cont'd)

2. Enhancing requirements of new technology and bio-tech products

- ❑ SFDA Approves Innovative Biotechnology-Based Diagnostic Test for the Early Detection of **Alzheimer's Disease**.
- ❑ SFDA updates their **requirements** and **guidance** to support innovatory in medical device software, enabling innovators, research centers, and investors to introduce modern technologies in the Kingdom.

✓ Guidance on Companion Diagnostic IVDs (MDS – G026)

✓ Guidance on Digital Health Products (MDS7 – G027)

Strategical Objectives (Cont'd)

3. Strengthen international collaboration and contribution

1. Team **Leader** For Arabic Translation Task Force (ISO/TC 210/ATTF)
2. SFDA **chair** and secretary of Technical Committee of Gulf medical devices and supplies (GSO/TC 11)
3. SFDA **chair** and secretary of the Arab Technical Committee for Standardization of Medical Devices and Supplies (AIDSMO/TC 4)

# of MD Committees in 2025	23
# of SC and WG in 2025	69
# of experts in MD National TCs in 2025	93
# of published and adopted MD standards till 2025	557
# of Technical Comments Raised By Saudi delegates until (2nd quarter) 2025	115

Strategical Objectives (Cont'd)

4. Improving Communication and Awareness with Health Care Providers and Public

❑ **New/updated** SFDA-MD Guidance

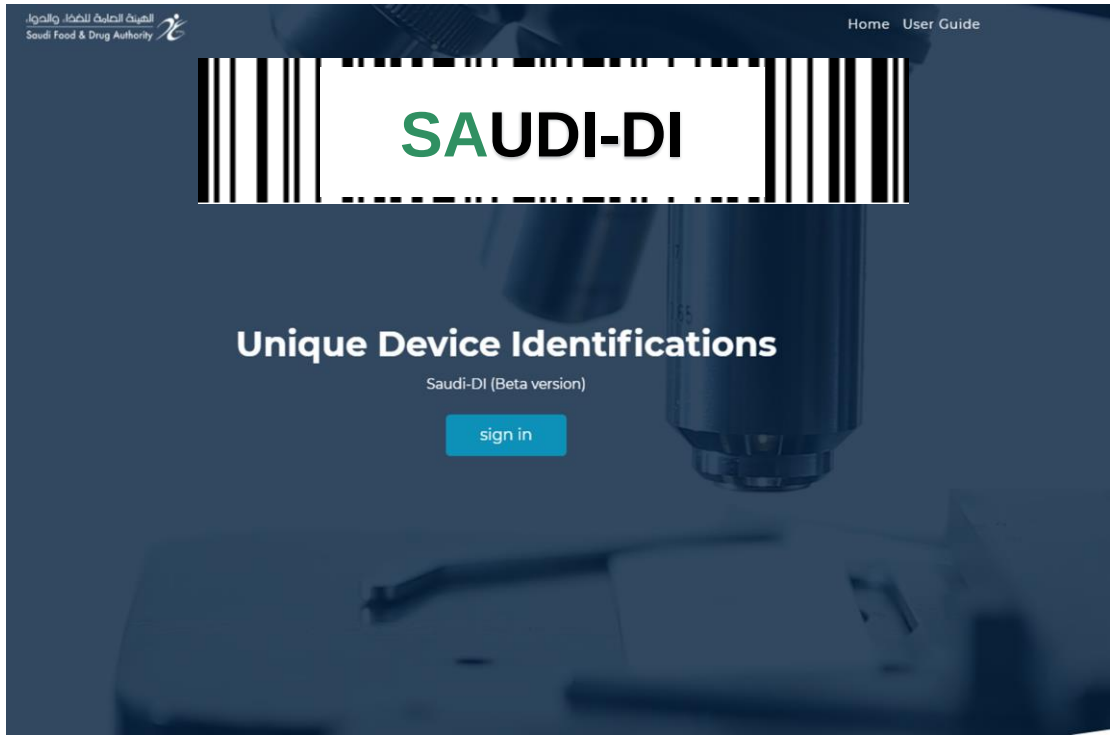
- ✓ Guidance for the operation and use of radiation emitting medical devices (MDS-G007)
- ✓ Guidance on the development of IVDs for in-house use (MDS – G022)
- ✓ **New** Guidance for ISO 13485 Requirements and Corresponding SFDA-MDS Requirements (MDS – G024)

Strategical Objectives (Cont'd)

- More than **21 workshops** were conducted for Health care provider in 2025
- Conducted **studies** with international, local universities, and experts.
- In addition, **more than 42 workshops** were conducted **covering 25 technical topics (for example MDMA requirements , innovative pathways .. ect)** to explain and clarify the requirements for MD manufacturers in 2025

SFDA Medical Devices Updates

- **UDI Compliance Timeframe**



MDS – REQ 7

Requirements for Unique Device Identification (UDI) for Medical Devices

# of Devices	445229
# of Accessories	44827
# of Manufacturers	1780

Post-market Surveillance Updates

Safety Alerts:

# Safety Alerts	**275** safety alerts affected the Saudi market out of **1281** globally detected	
Action Types	Correction **198**	Removal **77**
# Medical Devices Affected	**1,073856**	

Adverse Events & Complaints:

Received AE & Complaints reports	**82,503**		
Type of Reports	Healthcare providers **24238**	Manufacturers and companies **58086**	Public **179**

Officers of Healthcare providers: Officers Registered **1300**

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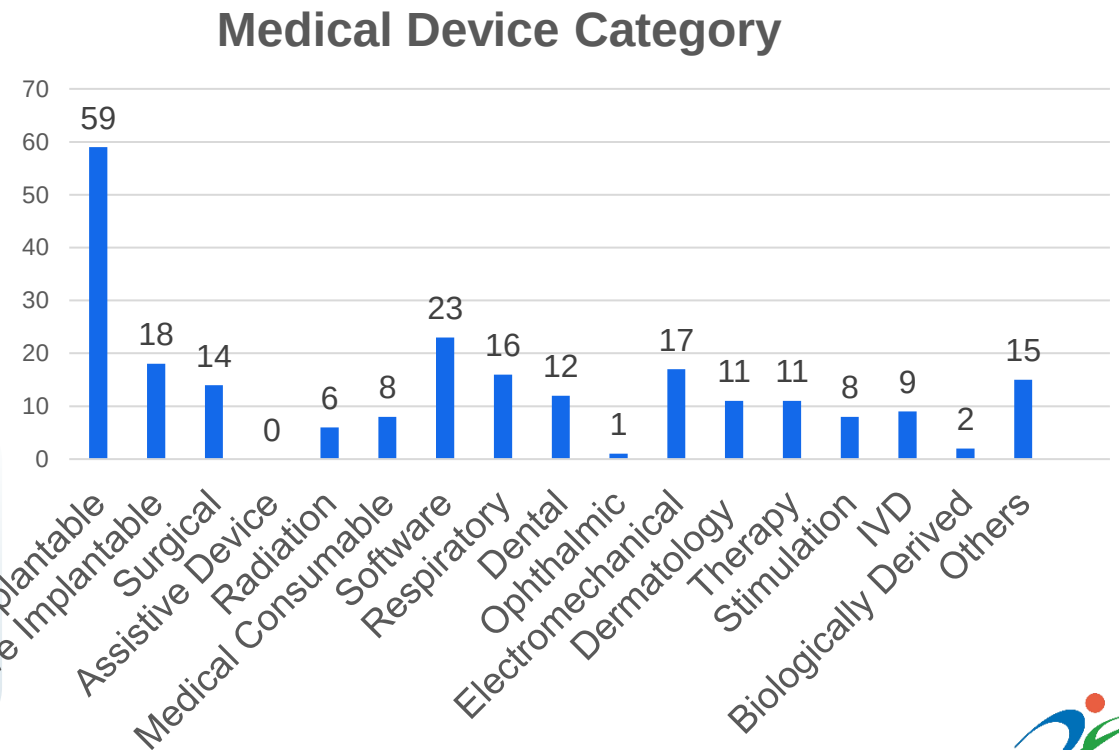
Clinical Trials of Medical Devices

During 2025, a total of 33 applications for medical device clinical trials were received and thoroughly evaluated

Total of 296 medical device clinical trial applications were submitted and reviewed, as shown in the table

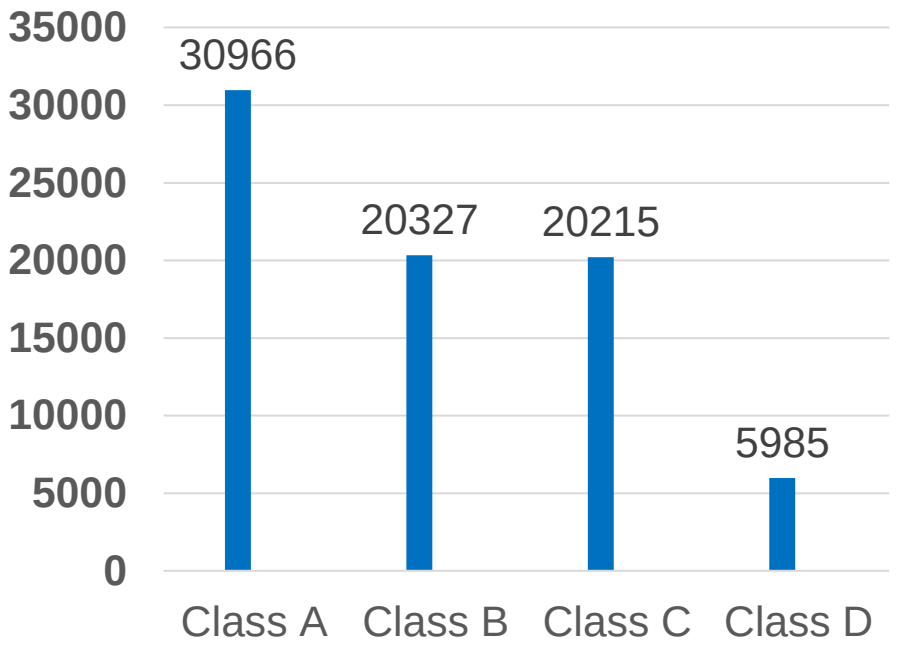


Marketing Authorization Statistics MDMA

Since January 2025, a total of 8119 applications were evaluated under the Scientific Evaluation section

Products Classification	Products
A	**30966**
B	**20327**
C	**20215**
D	**5985**

Scientific Evaluation statistics in 2025	
# Applications	**8119**
# Products	**77493**



National Diagnostic Reference Levels (NDRLs)

1. SFDA launched the first governmental initiative to establish **National Diagnostic Reference Levels (NDRLs)** in Saudi Arabia to optimize radiation doses in line with international guidelines and SFDA's strategic goals.

2. The SFDA had previously **published** NDRLs for imaging modalities such as:
   - Computed tomography CT (Adult and Pediatric)
   - General X-ray
   - Mammography.

<u>Now on 2025, the Saudi NDRLs is expanding to include nuclear medicine.</u>

3. Covers common protocols like:
   - Bone imaging
   - Thyroid, Renal, and Tumor imaging

4. This is to **enhance** diagnostic accuracy while minimizing unnecessary radiation exposure.

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Scientific Participation of the Saudi National Diagnostic Reference Levels (NDRLs) in Conferences and Scientific Fields

- Participation in the 4th International School Conference on Radiation Physics and Related Applications (Alpic School for Radiation Physics - ASRP 2025), which was held in Yerevan, Armenia, from June 16 to 21, 2025.

Guidance Under Development

Medical Device Cybersecurity Risks

Aim to regulate Manufacturers, Importers, and Healthcare Providers that develop software as MD.

Risk Communication for Medical Devices

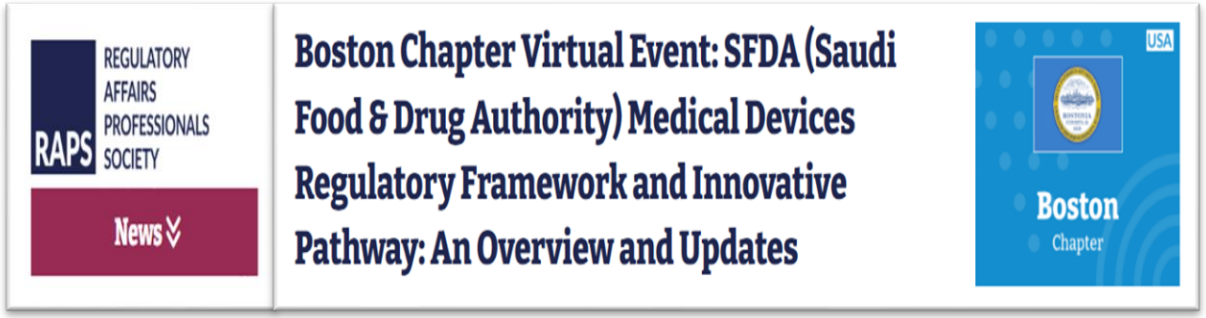
All medical device/IVD manufacturers, healthcare providers, and relevant stakeholders involved in the distribution and use of medical devices/IVD's

Guidance on Criteria of Medical Devices Bundling

Aim to bundle/group more than one type of medical device, including in-vitro medical devices (IVDs), within a single MDMA application.

News on International Activities

- **Recently, SFDA signed an MoU with the Association for the Advancement of Medical Instrumentation (AAMI)** to strengthen cooperation in MD, focusing on advanced technologies such as AI and biotechnology and standards development.



- **RAPS** held a virtual event on updates to the Saudi Food and Drug Authority's (SFDA) medical device regulatory framework, focusing on supporting innovation and simplifying market entry for medical devices in Saudi Arabia.

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Thank you/Questions

To access SFDA-MD Regulations and Requirements

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

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Update from the World Health Organization

Irena Prat, Team Lead
Prequalification Unit
World Health Organization

16 September 2025

Prequalification of IVDs

PQ listing of the first triple diagnostic test for ANC
PQ listing of the first HIV ST by urine

PQ expansion to haemoglobin point-of-care analysers

A new guidance document supporting the post PQ and EUL change request application process has been published and came into force on 1 June 2025

- webinar recording Passcode: 7YK=s?3=

Launch of pilot project for parallel PQ assessment and policy development

Launch of the ePQS portal

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WHO Emergency Use Listing for MPXV IVDs

Continued support to MPOX PHEIC response:

- 6 NATs listed, including PoC
- Ag RDTs not eligible for EUL as not recommended by WHO

Date Listed	Manufacturer name	Product name	Product code(s)	Regulatory version	EUL application number	Packaging	Link to access public report
3 October 2024	Abbott Molecular Inc	Alinity m MPXV assay (Alinity m MPXV Amplification (AMP) Kit & Alinity m MPXV Control (CTRL) Kit)	AMP kit: 09R06-095 CTRL kit: 09R06-085	USFDA EUA	MPXV-12644-027-00	Alinity m MPXV Amplification (AMP) Kit: 48 tests/tray, 192 tests/kit Alinity m MPXV Control (CTRL) Kit: 12 tubes per level	Available here
14 October 2024	Roche Molecular Systems, Inc.	cobas MPXV Qualitative assay for use on the cobas 6800/8800 Systems	cobas MPXV: 09863338190 Control kit: 09863320190 Buffer Negative Control Kit: 07002238190, 09051953190	USFDA EUA	MPXV-12647-046-00	cobas MPXV: 192 test cassette Control Kit: 1 x 16 mL Buffer Negative Control Kit: 1 x 16 mL	Available here
28 October 2024	Cepheid	Xpert Mpox	GXMPX-10	USFDA EUA	MPXV-12646-070-00	10 Xpert Mpox Cartridges with Integrated Reaction Tubes Disposable 300 µL Transfer Pipettes: Two bags of 12 per kit	Available here
06 March 2025	KH Medical Co., Ltd	RADIONE Mpox Detection Kit	RP001	Rest of the World	MPXV-13227-214-00	Pre-filled PCR Tube: 4 well-strip tube X 24 EA	Available here
09 May 2025	UStar Biotechnologies Ltd	EasyNAT Monkeypox Virus Assay	U202028-20	CE-Marked	MPXV-13201-208-00	20 cartridges, 1 positive control tube (1.2mL), 1 negative control tube (1.2 mL)	To be published
13 May 2025	UStar Biotechnologies Ltd	PortNAT Monkeypox Virus Test	U202031-20	CE-Marked	MPXV-13202-208-00	Box A: 20 cartridge-A, 20 swabs, 20 zip-lock bag Box B: 20 cartridge-B	To be published

New learning catalogue to upskill regulatory workforce

Health products regulation and prequalification learning catalogue

- WHO has launched a comprehensive learning resource to help countries build stronger systems for overseeing the safety, quality and effectiveness/performance of health products

- includes self-paced e-learning courses, instructor-led training sessions and on-the-job training experiences

Diagnostics coalition and definition

On diagnostics (including IVD and non IVD) Definition and Coalition

Background

- The 76th World Health Assembly on 30 May 2023, approved the WHA76.5 resolution named "Strengthening diagnostics capacity."
- The resolution included a footnote 1:
- *"For the purpose of this resolution, the term "diagnostics" includes medical devices used for the diagnosis, screening, monitoring, prediction, staging or surveillance of diseases or health conditions, both in vitro and non-in vitro types."*
- Requested:

(12) to develop and/or update WHO definitions of diagnostics, through a group of experts and public consultations, and to publish revised definitions before the 156th session of the Executive Board;

Process for definition

1st phase: collect information on definitions, 2024

2nd phase: subgroup of SAGE IVD and STAGMEDEV and WHO Dx.

3rd phase: NSA and consultation in April –May 2025. Address the 75 comments received.

4th phase: to conclude, reviewing all comments . by Q3

Outcome definition (26- August-2025)

- Diagnostics are those medical devices* intended by the manufacturer to be used, either **in vitro or non in vitro,** alone or in combination, for human beings, for providing information for one or more of the specific medical purposes:
- Diagnosis or monitoring of disease, Investigation; diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction or determination of physiological status.
- *In alignment with the International Medical Device Regulators Forum as: (IMDRF1): Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices, IMDRF/GRRP WG/N47 FINAL:2024 (Edition 2) published 26 April 2024.

World Health Organization

Global Diagnostics Coalition

WHO managed network to provide advocacy for strengthened diagnostics capacity

https://www.who.int/initiatives/global-diagnostic-coalition[1]

Medical devices nomenclature

Nomenclature medical devices, reported in the World Health Assembly WHA78.
Using EMDN and GMDN in WHO databases
on going updating and expansion of list

EMDN related code(s)

Z110101 LINEAR ACCELERATORS

The code(s) and term(s) in this section were observed and retrieved from public databases and have not been validated by health regulatory authorities. Please consult your regulatory agency and EMDN site:
https://webgate.ec.europa.eu/dyna2/emdn

GMDN related code(s)

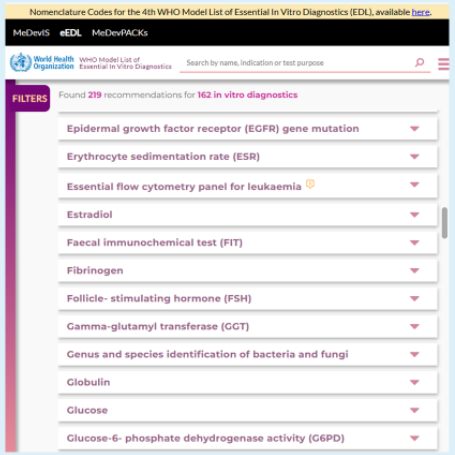
35159

Linear accelerator system (An assembly of devices designed to produce high-energy electrons to yield high-energy x-rays used for therapeutic applications, primarily to treat cancer. It provides a uniform radiation field of uniform intensity and predictable energy level, in a beam with well defined dimensions. The principle of operation is linear acceleration of electrons by means of electromagnetic (EM) microwaves. The output is used as a treatment beam on the patient, either directly or after passing a suitable target. The system typically includes signal analysis and display devices, patient and device supports, and software.)

The medical device term(s), code(s) and definition(s) in this section were retrieved from databases external to WHO. As there might be more than one name, definition and "Nomenclature Code" related to the specific medical device, please consult https://gmdnagency.org GMDN ®, © GMDN Agency 2005-2025

In the Medical Devices information system, version 2.1

In the Essential in vitro diagnostics list



In Medical devices packages

World Health Organization

https://medevis.who-healthtechnologies.org/

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Training materials for IVDs assessors

Finalization of training materials for assessment of IVDs technical files –beginner's courses

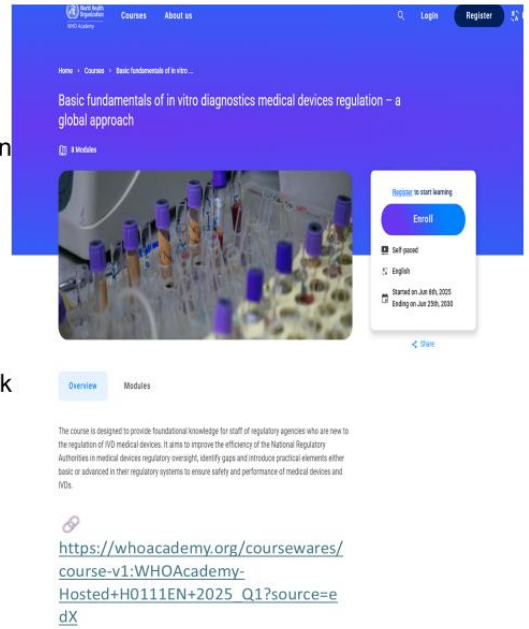
📢 **New WHO Training Course Launched!**

This course provides a foundational overview of IVD regulation, designed for regulators and all stakeholders involved in the lifecycle of in vitro diagnostics.

📘 The course includes six self-paced modules:

- ✓ An Overview of IVDs: A Regulatory Perspective
- ✓ Quality Management System and Risk Management Devices
- ✓ Performance Studies for IVDs
- ✓ Labelling Requirements
- ✓ IVD Market Approvals
- ✓ Post-Market Surveillance

🌍 Strengthen your understanding of global regulatory principles and best practices in IVDs.



https://whoacademy.org/coursewares/course-v1:WHOAcademy-Hosted+H0111EN+2025_Q1?source=edX

📢 **Validation of training materials on assessment of IVDs technical files**

- ✓ WHO piloted training materials on IVD dossier assessment at the WHO Academy with assessors from 12 NRAs.
- ✓ 23 to 26 July 2025
- ✓ The materials have 17 modules covering key regulatory elements emphasizing the scientific principles necessary for assessing IVD safety and performance.
- ✓ The materials are aligned with WHO and International Medical Device Regulators Forum including use of Table of Contents for compiling IVDs technical.
- ✓ Finalization in Q4/2025

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Supporting manufacturers and regulators for post-market and market surveillance

- Regulators
  - Renewed focus to strengthen national capacities using WHO global benchmarking tool for medical devices
  - In September, WHO will support 7 African countries to self-benchmark themselves against these regulatory functions
    - National Regulatory System (RS);
    - Post-market surveillance, market surveillance and control (PS)
    - Licensing establishments (LI)
  - Link to Evaluation of national regulatory systems of medical devices (GBT+ Medical devices)
- Industry
  - From October 2025, WHO Global Surveillance and Monitoring System for substandard/falsified medical products (GSMS) will allow manufacturers to directly report incidents and FSCA through the GSMS portal
  - Portal onboarding will include lessons on IMDRF adverse event reporting terminology

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GBT+MD and technical support

Capacity Strengthening:

- Renewed focus on building national regulatory capacity through application of the WHO Global Benchmarking Tool for Medical Devices (GBT+MD) and evaluation of regulatory systems.

WHO-Listed Authorities (WLAs):

- Active discussions across the three levels of WHO to define applicability, criteria, and steps towards listing NRAs as WLAs for medical devices.

WHO CIP Network:

- Recommendation from the 19th ICDRA to extend scope of support to include medical devices.

Link:

- Evaluation of national regulatory systems of medical devices (GBT+ Medical devices)

NATIONAL:

Senegal

- **Activity (Sept 2025):** Assisted Self-Benchmarking mission
- **Objective:** Conduct assisted self-benchmarking of Senegal ARP using the WHO GBT+MD
- **Expected Outcome:** Completed self-benchmarking report with documented strengths, gaps, and updated IDP recommendations for further support.

REGIONAL:

African Region

- **Activity (Sept 2025):** WHO Regional Assisted Self-Benchmarking mission on Medical Device Regulation (GBT+MD) in Africa.
- **Objective:** Build NRA capacity to assess regulatory systems for medical devices with a focus on RS, LI & PS functions.
- **Expected outcome:** Identified strengths, gaps, and priority actions documented in IDPs to guide follow-up support.

Region of the Americas

- **Activity (Sept 2025):** Webinar on Medical Device Regulation & GBT+MD.
- **Objective:** Strengthen NRA capacity using WHO frameworks and tools.
- **Outcome:** Enhanced knowledge of GBT+MD, regulatory frameworks & surveillance.

Upcoming events: UN meeting with manufacturers

- 2025 Joint UNICEF-UNFPA-WHO Meeting with Manufacturers and Suppliers
- 29 September to 3 October 2025. Sessions will be held daily from 11:00 AM to 03:00 PM (CEST)
- ***Delivering in times of Disruption: Building resilient, quality supply systems for sustainable impact***
- Fully virtual event

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Thank you!

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Questions?