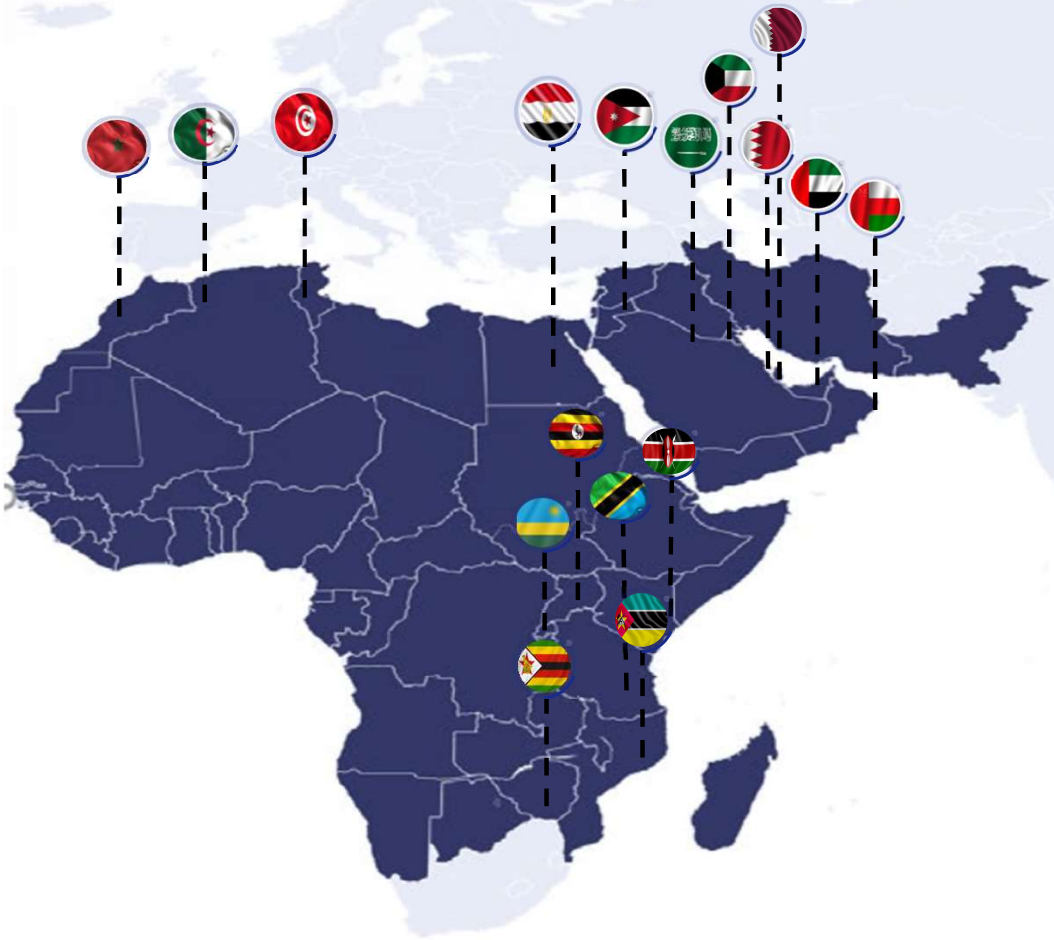

Regulatory updates from Middle East & Africa

Rana Chalhoub
RA Director – Mecomed
Feb 2023

SAUDI ARABIA

- **UDI:**
  - Bulk upload tool still under development
  - Refer to latest guideline for list of attributes: MDS – REQ 7 (V4),

Compliance Timeframe	
Launching the UDI database and starting optional registration for all type of devices	1st October 2020
Risk Class	**Compliance date**
Class B & C (Medium risk) Class D (High risk)	1st September 2023
Class A (Low risk)	1st September 2024

- **Hague Convention**

As of December 7, 2022, Saudi Arabia became the newest participant in the Apostille Treaty, created at the Hague Convention in 1961.

- https://www.hcch.net/en/instruments/conventions/status-table/?cid=41

- **Class 1 enforcement:**
  - Starting from Sep 2022, low-risk Class A (non-sterile, non-measuring, non-reusable) have to be registered through MDMA-2. The required documents for this class are identified in REQ 1 “Annex 3”.

- **New template for the Saudi AR Mandate**

- **Variation:**
  - New Draft Guidance published for comments in Jan 2023 on MDMA Significant and Non-Significant Changes.

- **New Import/Export portal** by MOHAP for shipment release.
- Data Loggers shipping requirements.
- GS1 Tatmeen platform enforced for Pharma.

UAE

- Extension of the grace period for submission of product registration dossiers until August 2023.
- 90 days for queries' response.

KUWAIT

- MD establishments to start pilot registration files of high-risk medical devices that have MDMA approval in Saudi Arabia.
- The product application has 11 sections to be filled in.
- No fees in place in yet.
- Oman Draft Guidelines for Medical Devices Reporting – published for comments in Jan 2023
- Data Loggers requirements by April 2023.

OMAN

- NHRA deadline for Authorized Representatives registration- Jan 2023.
- Revised draft for Medical Device registration – published for comments in Jan 2023.

BAHRAIN

- New IMD registration application form (Manufacturer details, IMD related documents, additional documents).
- The expiry date of registration approval will be based on the validity of the submitted EC certificates for the devices.
- Attestation of some documents are requested.

QATAR

JORDAN

- **Jordan:**

- Extension of deadline for Class IIb medical devices registration until July 1st, 2023.
- Accelerated pathway for registration of Class II b medical devices that have been regularly imported to Jordan during the last 3 years.
- New Guidance addressing post-registration changes for medical devices.
- Circular clarifying the minimal required elements to be included within the finished product specification and composition.
- Updated draft for medical device regulation – shared for comments.

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EGYPT

- EDA updating current process for evaluation of case studies studies for medical devices that are transitioning from MDD to MDR with respect to IFU/labeling changes.
- UDI session on international practices delivered for EDA in December 2022.
- EDA presented at our Q4 meeting regarding the new registration process of In Vitro Diagnostics in Egypt, and medical devices requirements.
- A capacity building session on “Scientific Evidence for Safety and Effectiveness of Medical Devices-Pharma vs MedTech : Two Different Worlds… One Health Setting” for EDA on Feb 9.
- Vigilance Requirements.

North Africa French Speaking

ALGERIA

- Possibility to continue placing on the market of MD & IVD in Algeria, as long as they have CE Mark, for an additional 12 months - pending the amendment of the executive decree No 20-324 related to the homologation and distribution of medical devices and in vitro diagnostics.
- Link to press conference (no official circular published yet).

MOROCCO

- Special conditions that were in place during COVID (mainly regarding expired documents) be ceased by April 1st, 2023.
- Information of a proposed draft mandate to create a new entity AMMPS to oversee and regulate medical devices & pharmaceuticals in Morocco.

TUNISIA

- MOH note clarifying the conditions of importation related to Medical Devices with an expired MDD certificate, awaiting MDR approval.

- Phased approach for regulation – starting from Oct 2022.
- Grace Period → 24 months
- STED requirements in place.
- PVOC for unregistered products.
- 3 registration tracks: For GHTF approved products and WHO PQ (90 days) and Rest of the world (250 days).

UGANDA

- Guidelines on submission of documentation for registration of medical devices”
- Guidelines on submission of documentation for registration of in-vitro diagnostics”
- Manufacturing site inspections fees
- Local export, import or manufacturer should register themselves with Rwanda FDA

RWANDA

- **Zimbabwe:**
  - Products in scope of registration: Gloves and condoms
  - Guidelines currently under process:
    *Regulations of In-Vitro Dianostics
    *Regulations for Import and exort control of MedTech
    *Regulations of PPE
    *Regulations of local production and distribution of Medical devices

ZIMBABWE

GMTA Africa WG:

- Aims at aligning the MedTech Industry (Associations) on a common strategy towards Africa region and creating synergies to optimize resources and ensure deliverables.

- Create a collaborative approach with regional African bodies to accelerate MedTech regulatory convergence and adoption of international standards and good regulatory practices, as they pertain to medical technology.

Medical Device Regulatory Convergence(MDRC) Project:

African Medical Devices Forum

- Mecomed engaged in MDRC project supported by USAID and led by Advamed, envisioned for Kenya, Ghana and South Africa.
- Operating via two tiers:
  - Tier 1 focuses on implementation of GRP and TBT requirements in a whole of government approach
  - Tier 2 looks at advancing regulatory convergence for Medical Technology sector and support efforts of the African Union Development Agency(AUDA-NEPAD) and relevant Technical Working Groups and subgroups including the Africa Medical Devices Forum (AMDF)

F2F Engagement with key stakeholders in Kenya

- Several meetings in Nairobi, Kenya the week of 23-27 January, as part of MDRC delegation. Engagements included:
- the Kenya Pharmacy and Poisons Board (PPB)
- the Africa Medical Devices Forum (AMDF)
- The Kenya Bureau of Standards (KEBS)
- The African Regional Organization for Standardization (ARSO)
- The Medical Technology Industry Association of Kenya (MEDAK)
- The Kenya National Chamber of Commerce and Industry
- The AmCham Kenya

Mecomed Current Working groups:

UDI WG:

- Working on a recommendation paper for UDI regulations in the region – Expected to be published in Q1, 2023.

MDR/IVDR WG:

- Aiming at addressing the impact of the EU MDR/IVDR Regulation on the registrations in the region, from assessment to communication, up to capacity building initiatives.

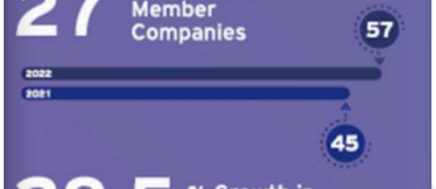
Regulatory Training for Mecomed Distributors:

- Training program for distributors in the region around regulatory documentation and product lifecycle from pre-market, on market and post-market perspective.

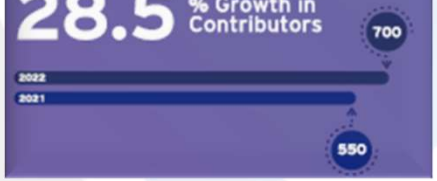
MECOMED IN NUMBERS 2022

Membership

27 % Growth of Member Companies



28.5 % Growth in Contributors



Regional/International Presence

- Introduced KSA Chapter
- Chaired GMTA Africa Working Group

Events

- Hosted **4** events
- Total attendees **800+**
- Participated in **6** third-party events

Advocacy

In The MEA Region

Commented on 10 regulations/ laws

Conducted 12 roundtables on regulation/legislation in Egypt, Jordan, Kuwait, Oman, UAE, Kenya & the rest of Africa

Completed a research project on HTA for Medical Devices

Contributed to 2 whitepapers on data privacy (GMTA)

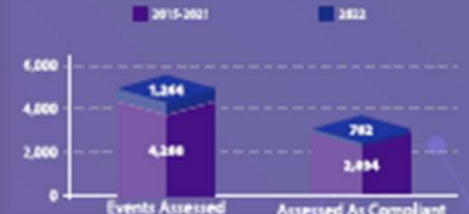
Trainings & Capacity Buildings

280 trained on Regulations

185 trained on Market Access

800 trained on Compliance

Conference Vetting System



Communication

Shared **105** regulatory circulars and updates to the members

How about 2023?

The journey continues with a focus on

- Contributing to shaping the regulatory policies in the region
- Commitment to capacity-building initiatives
- Raising awareness around good regulatory practices & Technical Barriers to Trade
- Driving efficiencies and agility through Regulatory Convergence and Reliance
- Digital Health Regulations
- Stakeholders' engagement and collaboration is Key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“If you think compliance with regulations is expensive, try non-compliance”
Paul Singer