mecomed

Medical Technology Association

Middle East and Africa

Who We Are

Mecomed is the trade association representing the medical devices, imaging, & diagnostics industries in the Middle East and Africa.

Our Mission

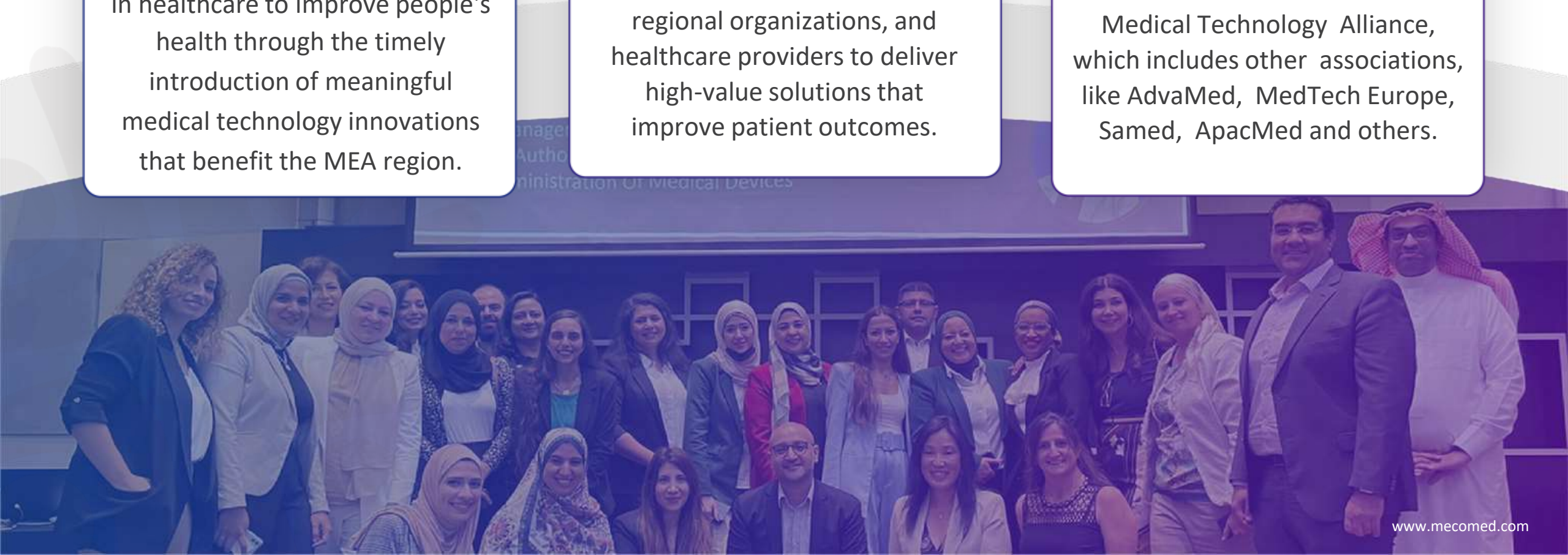
Bring together all stakeholders in healthcare to improve people's health through the timely introduction of meaningful medical technology innovations that benefit the MEA region.

Foster Good Citizenship

Collaborate with governments, regional organizations, and healthcare providers to deliver high-value solutions that improve patient outcomes.

Our Association

Mecomed is a member of Global Medical Technology Alliance, which includes other associations, like AdvaMed, MedTech Europe, Samed, ApacMed and others.



Our Members 2025

mecomed

Our Associate Members 2025

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Mecomed Board 2023-2025

Mecomed Chairman

MAHER ELHASSAN

BD

FARAH N. HAMDAN

ZIMMER BIOMET

HANI KHASATI

ABBOTT

MAJDI YOUNIS

CONVATEC

MAZEN TAKHAH

JOHNSON & JOHNSON

QUSAI AL-SAYYED

BIOMÉRIEUX

ROULA YOUSSEF HALABI

COOPERSURGICAL

TAREK EL RAHBANI

BOSTON SCIENTIFIC

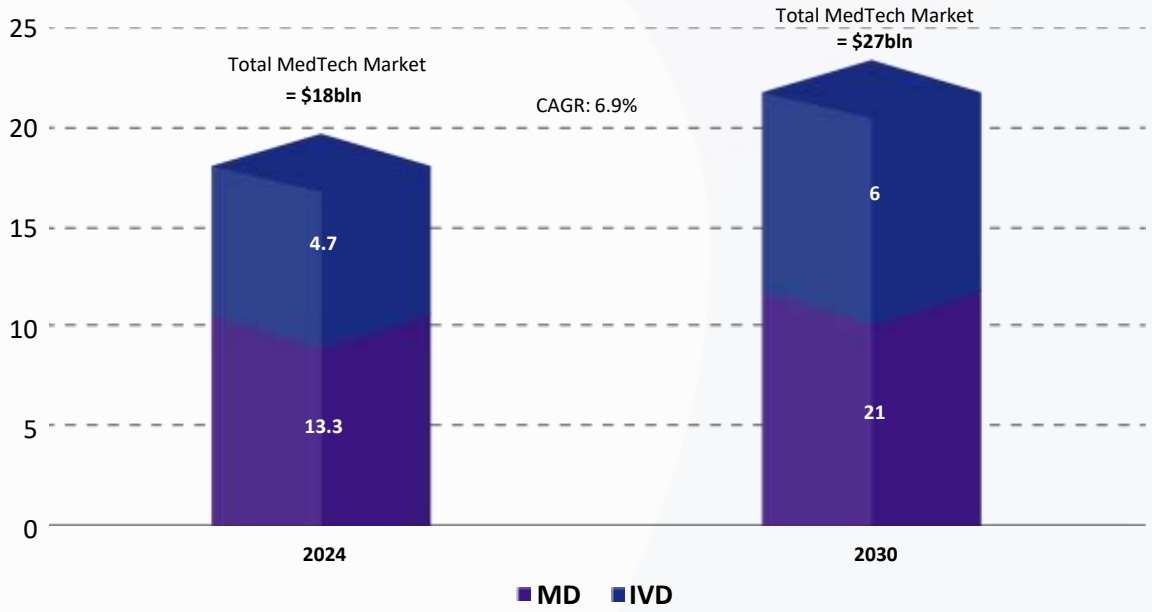
MEA MedTech Market

2.05Billion
Population

Country Healthcare Expenditure range: **from under $15 to over $2300 per capita**

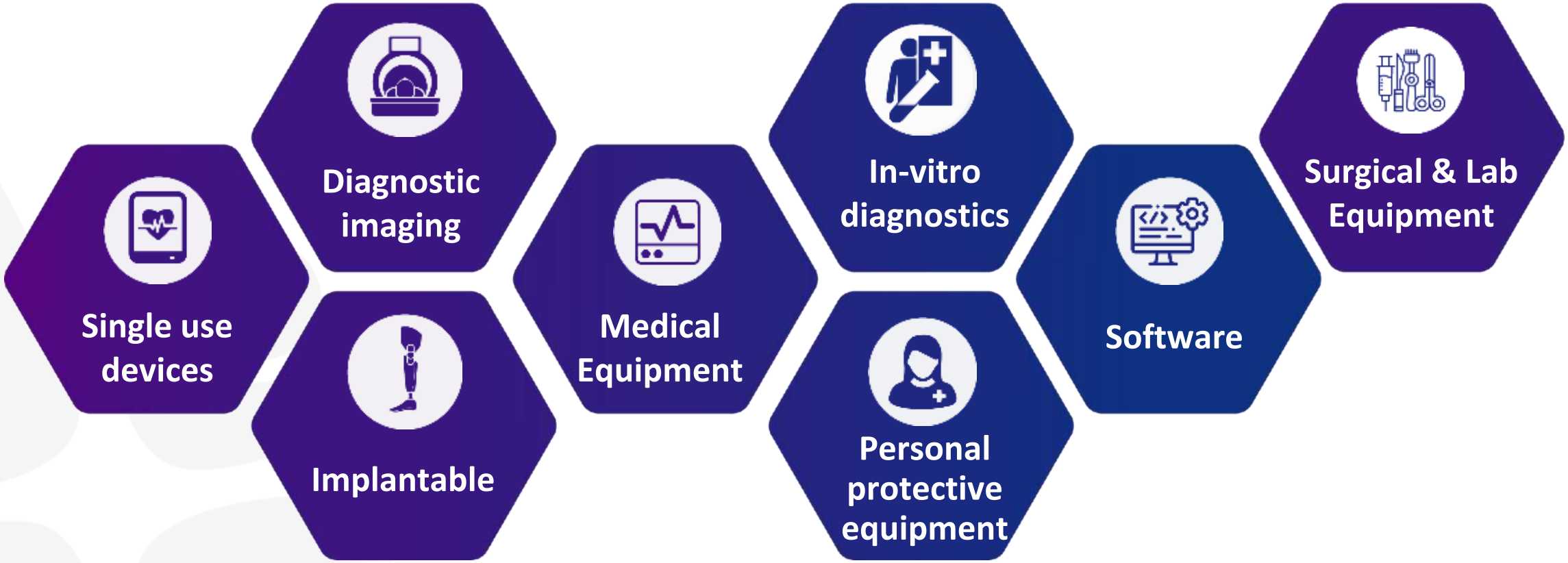
Country Healthcare Expenditure range in% of GDP in MEA: **2.5% to 10%**

MEA MEDTECH MARKET SIZE



MD: **7.88%** **CAGR 2024-2030** IVD : **4.1%**

Most Common Uses of Medical Devices



https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature

Our Stakeholders

- Patients
- Healthcare professionals
- General public
- Governments
- Insurance companies
- Medical Technology companies
- Distributors and other partners
- Regulators

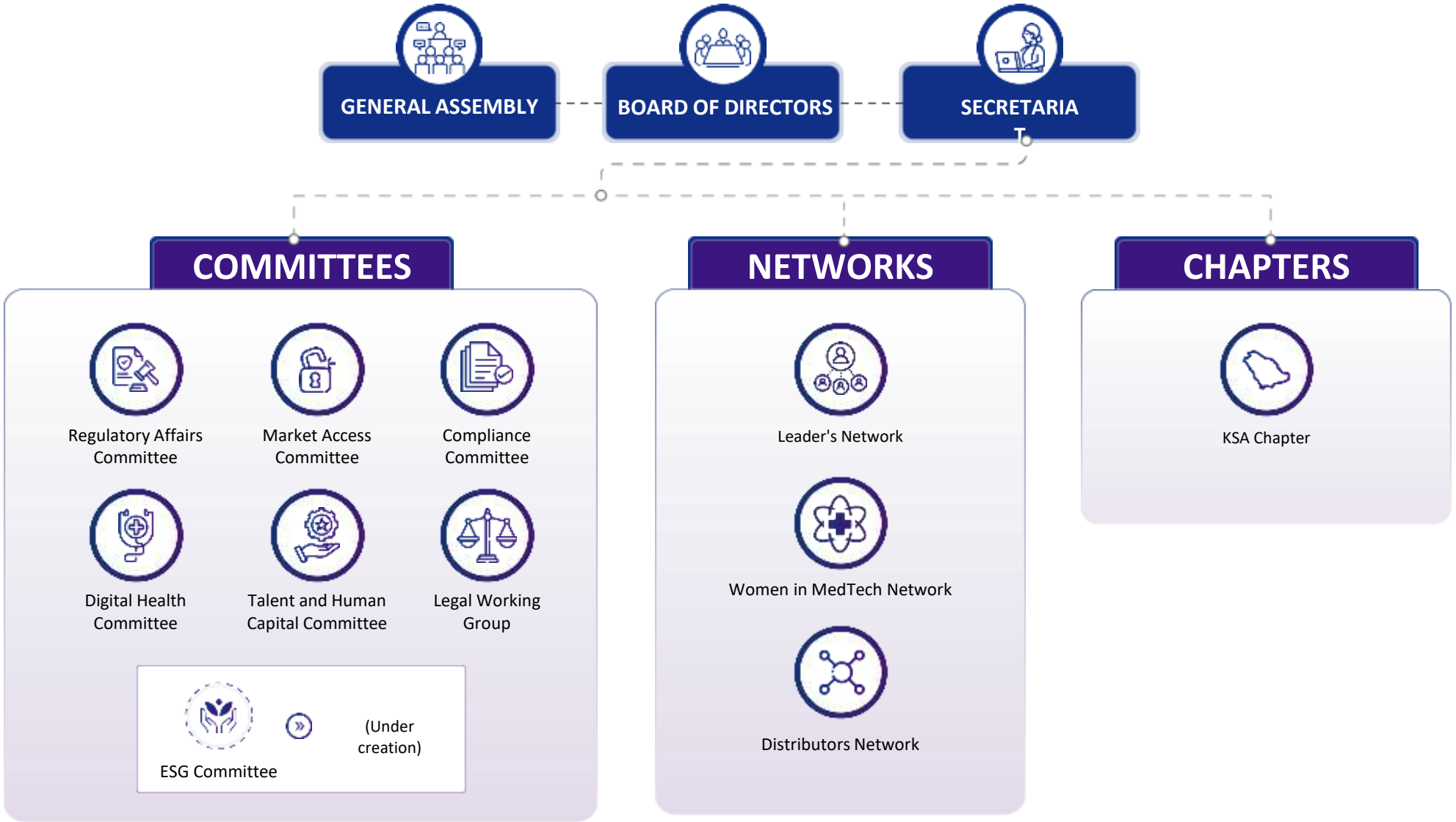
The Value We Add

- Enable faster access to the latest medical technology and innovation
- Help shape an ethical and sustainable healthcare environment
- Partner with and bring together all the different stakeholders of Medical Technology industry
- One voice in addressing issues facing the industry and healthcare in general
- Direct channel of communication with healthcare authorities across the region

Members' Benefits

- Be part of collective voice focused on improving standards of care in MEA
- Participate in dedicated sessions of functional committees and working groups
- Benefit from exclusive market insights and regulatory intelligence
- Join workshops, seminars, trainings and other industry events at special rates
- Elevate your brand by being acknowledged as Mecomed member

Mecomed Org. Structure



Regulatory | Compliance | Market Access | Talent & Human Capital | Legal | Digital Health

Members Benefit From:

Synergy of unified industry approach to ensure issues are escalated & discussed properly with authorities & awareness is created in alignment with international standards.

Sharing best industry practice among member companies and educational sessions for the committee members on key RA topics globally and regionally

Access to database information on the regulatory requirements per country and other related regulatory topics

Well established partnership with regional regulators regarding regulatory matters & capacity building initiatives

First-hand members updates on the regulatory changes in the region

Regulatory | Compliance | Market Access | Talent & Human Capital | Legal | Digital Health

Current Group Priorities

Actively engaging in shaping the regulatory policies in the region, by communicating the latest regulatory intelligence, and advocating industry challenges and priorities.

Raising awareness around good regulatory practices, convergence and reliance, and addressing MDR/IVDR impact on the regulations in the region.

Building capacity initiatives with internal and external stakeholders: educational sessions and training for members and regulators.

Developing and delivering a regulatory training program for Mecomed distributors around RA documentation and product lifecycle.

Cross Collaboration with GMTA and other trade associations on global topics and Africa.

Raising awareness around Digital Health Regulations and trends, such as E-IFU, green submission, UDI & others

MEA Regulatory Environment

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01 Dynamic Open Market Regulatory Controls

02 GHTF Based Regulation In-Country Requirements

03 Pharma Driven Requirements and Digital Technologies

04 Impact of International Changes on Local Registrations

05 Growing Focus on Post-Market Surveillance & Traceability

Be Informed

- Regulatory Intelligence & Updates
- Sharing Best Practices

Anticipate Change

- Capacity Building Initiatives
- Members' Training & Education

Respond with Confidence

- Solid Databank
- Engaging with Authorities & Trade Associations

RA Working Groups

Different Working groups are in place to cater to the industry priorities and emerging topics

Promoting a Green Submission Initiative under ESG umbrella:

- Mecomed Paper around e-IFU (Electronic Instructions for Use) for Professional users of Medical Devices
- Mecomed paper on electronic signature
- Mecomed paper on US electronic export documents

Impact of changes under EU MDR&IVDR Regulation to International Registrations:

- MEA Impact Assessment
- General communication + Proposal to the authorities for the way forward
- Capacity building on MDR / IVDR for members & authorities

Latest EU MDR Amendment

- Webinar on the amendment

***attended by 12 different NRAs**

Distributors' Training

- A training curriculum for distributors' including technical file, Quality management system, UDI, Post Market Surveillance and MDR/IVDR.

***Over *400 attendees* trained from *200* different distributor companies in MEA region**

RA Working Groups

Different Working groups are in place to cater to the industry priorities and emerging topics

UDI Working Group

- Looking into a harmonized implementation of UDI across the region.

***Published a paper about UDI industry recommendation**

Reliance WG

- Promote regulatory convergence and good reliance principles, as part of Good Regulatory practices and reducing Technical Barriers to Trade in International & Regional forums.

Pre & Post Market requirements in MEA Region

- Map out the registration, importation and post market surveillance requirements in MEA region.

Capacity Building WG

- Streamline and develop different capacity building initiatives for the various stakeholders: internal & external.

***Over 25 educational sessions delivered to the different stakeholders**

MECOMED: a trusted partner to the authorities of the region

Bringing the Best-in-Class regulatory expertise to the region: Several regulatory capacity building initiatives for Regulators & SMEs in Middle East & Africa

- √ Good Regulatory Practices &Implementation of an Effective Regulatory System
- √ EU MDR & IVDR Regulation – Main Changes & International Impact
- √ EDA Vigilance Training & Post Market Surveillance
- √ Japanese Jurisdiction
- √ Clinical trials training
- √ Training on MDR Documentation
- √ EDA Vigilance training
- √ Workshop on MD&IVDs Regulatory Framework

- √ Regular Industry Meetings with SFDA

- √ Technical File Documentation
- √ 3D - Printing
- √ EU IVDR – Bundling & Classification
- √ Oman Medicated Medical Devices Workshop

- √ GCC Summit on Medtech Regulation & Market Access

- √ Legal Manufacturer and MD Documentation

- √ EU MDR & IVDR Regulation: Main Changes & International Impact

- √ EU MDR Regulation: Changes & Transition Timelines
- √ Traceability & Vigilance Reporting

- √ MDRC Initiative: Kenya & Ghana
- √ GMTA Africa Working Group
- √ Kenya GRP & Technical Competencies workshop
- √ PAC workshop - GRP as a market enabler for trade

- √ Good Regulatory Practices & Implementation of an Effective Regulatory System
- √ Training on EU MDR & IVDR to DRAP

Exclusive Educational Sessions for Regulatory Committee Members

- Medical Technology Post Market Surveillance & Vigilance
- EU MDR/IVDR: A game changer for Europe: How will this impact your MEA Registrations – Continuous update on the state of Implementation.
- Unique Device Identification (UDI)
- Non-Medical Regulations in MEA
- GRP & Technical Barriers to Trade
- International Benchmarks & the impact for MedTech.

Exclusive Educational Sessions for Regulatory Committee Members

- EU Commission Proposal to extend MDR transitional period - MedTech Europe
- Digital Health Regulations - AKRAteam
- Recent Developments in Regulation for Advanced Technologies in Medical Devices - Any Chen
- UK regulations & the way forward – ABHI
- US Electronic export Documents & International impact - AdvaMed
- Key regulatory trends for 2023 & Expectations for 2024
- Session on EU AI Act & implications for MedTech

On-Going cooperation with International & Local Trade Associations

MedTech Europe: MEA Working Group, MTE Quarterly Webinars

GMTA Africa Working Group

Samed / SALDA in South Africa

Advamed: MDRC Project in Africa

Local Associations: MEDAK, HDAP, …

Regulatory | **Compliance** | Market Access | Talent & Human Capital | Legal | Digital Health

Members Benefit From:

- The Conference Vetting System (www.ethicalmedtech.eu)
- Trainings of members and other stakeholders on Mecomed Code and CVS.
- Established escalation process and successful conflict resolution
- Access to Disclosure Platform
- Instilling the Code of Ethics, based on principles of separation, transparency, equivalence & documentation
- A library of guidance, templates/forms/Trainings and other supporting documents

Current Group Priorities

- Awareness & Trainings: Continuous trainings on the Code & CVS
- Africa Working Group – better focus on Africa & better support
- Compliance alignment and collaboration with other MedTech associations
- Working with Authorities and Regulators in the region
- Transparency and Disclosure platform
- Distributors & TPIs: Certification project & Associate membership
- Conflict Resolutions and Escalation process
- Mecomed Code Enforcement

Compliance Initiatives

Changing Behaviors & Mentalities & build a culture of compliance

Safeguard for the industry - Ethical Perception

A Level Playing Field with equal chances to succeed

Conference vetting System (cvs)

CVS is an independently managed system which reviews the compliance of Third-Party Educational Events with Mecomed Code of Ethical Business Practice to determine the appropriateness for companies which are members of Mecomed to provide financial support to such events in the form of Educational Grants or commercial activities (e.g., booths, advertising, satellite symposia etc.).

Members of Mecomed and their Third-Party Intermediaries (TPIs), cannot provide support to any Third-Party Educational Event, unless it is assessed **Compliant** by CVS in advance. Furthermore, the decisions rendered by the CVS Compliance Officer are binding on Mecomed members and their TPIs. In practice, this means that no support can be provided to a Third-Party Educational Event which is not assessed as **"Compliant"** by CVS.

Assessment Criteria:

- **The scientific programme**
- **The geographic location**
- **The conference venue**
- **Hospitality**
- **Registration fees**
- **Communication support**

Conference vetting System (cvs)

What you need to know about CVS

Submissions must be made online via the Ethical MedTech Conference Vetting System website: www.ethicalmedtech.eu

Submission must be done **no later than 50 days** prior to the Event starting date.

Needed documents and information to finalize the assessment:

» Communication support (Website, Brochure or flyer)
» Name of the venue
» Detailed agenda of the program
» Registration fees

No charges apply when submitting an Event in CVS

Different stakeholders can do submissions in CVS:

» Professional Conference Organizers (PCOs)
» MedTech / Mecomed Members and their TPIs
» Medical Societies and Healthcare Organizations (HCOs)

Mecomed CVS Officer Contact:

Ruba Khasati
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Email: ruba.khasati@live.com

Regulatory | Compliance | **Market Access** | Talent & Human Capital | Legal | Digital Health

Members Benefit From:

An understanding on the healthcare systems land scape for the countries of interest and tracking healthcare reforms

Ongoing education on key health economics, HTA and market access topics

Promoting the concepts of value-based procurement and industry-friendly HTA to key stakeholders in the region

Regulatory | Compliance | Market Access | Talent & Human Capital | Legal | Digital Health

Current Group Priorities

- Stakeholder engagement on Value-Based Healthcare and Value-Based Procurement
- Leveraging WHO Resolution on Strengthening Diagnostics Capacity
- Advocating for best practices of HTA and Reimbursement for Medical Devices with relevant stakeholders in the MEA region
- Building Capacity of internal and external stakeholders on Market Access for MedTech

Regulatory | Compliance | Market Access | **Talent & Human Capital** | Legal | Digital Health

Members Benefit From:

Ongoing support in the C&B benchmarking process

Sharing best Talent Management practices, both global and regional

Continuous spot legal/ employment updates including localization programs

Regulatory | Compliance | Market Access | **Talent & Human Capital** | Legal | Digital Health

Current Group Priorities

- Knowledge Exchange on common HR challenges with global experts
- Internship initiatives within the industry for developing future workforce
- Embracing Diversity and inclusion and leading Women Leadership initiatives
- Building internal capacity on talent management and personal development

Regulatory | Compliance | Market Access | Talent & Human Capital | **Legal** | Digital Health

Members Benefit From:

Monitoring of legislation changes and enforcement in MEA countries

Attending & participating in presentations / trainings from external lawyers and / or subject experts around topics proposed by members and decided by the Legal Working Group

Sharing best practice, in line with applicable laws

Regulatory | Compliance | Market Access | Talent & Human Capital | **Legal** | Digital Health

Current Group Priorities

- Providing on-going legal support to the association on publications, contracts, positions/statements, as well as guidelines and internal policies
- Conducting recent policies impact analysis
- Legal updates to Leadership group and Committees and supporting Mecomed with legal advice
- Engaging in several task forces to provide a position paper on certain legislations

Regulatory | Compliance | Market Access | Talent & Human Capital | Legal | Digital Health

Members Benefit From:

Strong relations and communication channels with regional governing bodies on healthcare data and digital health laws

Subject matter experts' advisory to the committee on developing regulations/ legislations pertaining to digital solutions & data privacy

Member-only alerts on changes/ developments in the digital health landscape of the region

Networking opportunities with peer members and subject matter experts

Regulatory | Compliance | Market Access | Talent & Human Capital | Legal | Digital Health

Current Group Priorities

Value and Reimbursement of Digital Healthcare Technologies :

Understanding the value and reimbursement of digital technologies in MEA; advisory on adoption, opportunities, & barriers to market access

Interoperability & Data Governance:

Influencing & building consensus on digital health and data privacy regulations in the region

AI in Healthcare:

Engaging with the regional key stakeholders on co-creation of AI Regulations for healthcare

Women In MedTech Network Purpose

Vision:

Pioneering a MedTech ecosystem where women lead innovation, shaping a future where diversity is the cornerstone of healthcare advancements in the Middle East.

Mission:

Empower, connect, and elevate women in MedTech through mentorship, leadership development, & strategic collaboration, breaking down barriers and fostering inclusion.

Goals:

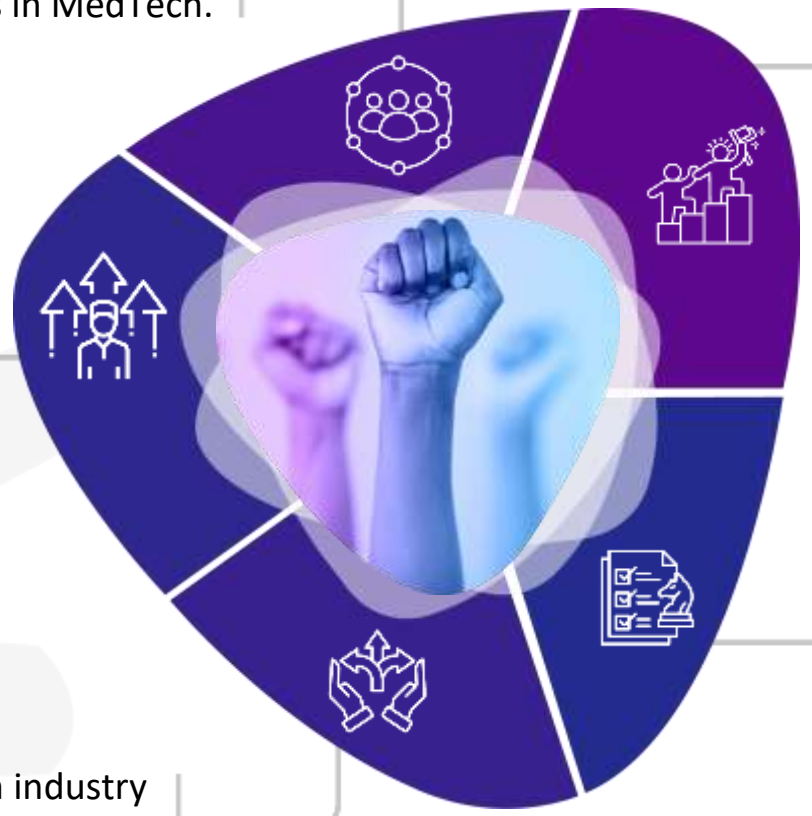
- Drive 15-20% of female representation in leadership roles across the MedTech sector by 2030
- Launch cross-industry partnerships and establish a sustainable support network for continuous professional growth
- Ensure gender equality and benefits across the industry.

Women In MedTech Network Benefits

A supportive, empowering community committed to breaking glass ceilings in MedTech.

Build powerful connections with industry leaders and like-minded women in MedTech.

Gain career acceleration advice, leadership skills, and professional development support.



Elevate your visibility and influence through strategic networking in the region.

Personalized guidance from industry experts who have successfully navigated their careers.

Distributors' Network Vision & Mission

To develop a strong Industry Network joining both Manufacturers and Distributors to ensure a smooth, efficient and ethical transfer of the latest Life Saving Solutions and Technologies to our geographies keeping patients first.

We will be able to achieve that through our cooperation in addressing barriers & concerns hindering the efficient transfer of technology with key stakeholders & through the upgrade of the solutions and services we offer.

Mecomed’s Distributors’ Network

Benefits

- Adding your voice to Mecomed’s in addressing local and regional issues
- Voicing Distributors’ concerns for a better reach and exposure with industry and with healthcare Authorities
- Joining forces in addressing issues related to Privacy, Tenders, Access and Digital Health
- Join lobbying meetings with Authorities
- Access to educational/Informational sessions and introductions to various emerging topics like ESG,
  D&I and Digital Health
- Increased exposure to the Industry, guiding rules
  and regulations
- Being Acknowledged as Mecomed Associate Members (When Joining Mecomed as AM)

Why

- Our distributors are the industry partners and extension
- They represent us in various markets and under various forms
- They are the trusted connection in transferring technology and bringing solutions to the patient
- They are potential future joint partners and core presence in any given geography
- We need to cooperate to ensure that the voice of
  the industry is heard and that the issues affecting
  the industry altogether are discussed and that the proper solutions are proposed

Who

- All distributors of existing Mecomed Members are welcome
- Representatives of distributors leadership and some specific functions to populate this network
- Management
- Regulatory
- HR / Compliance
- Market Access / Digital Health

KSA Chapter

Vision

To foster collaboration, innovation, and compliance to drive the transformation of healthcare and improve patient outcomes in alignment with Saudi Vision 2030.

Mission

» To build a robust network of stakeholders across the Kingdom to:

» Collaborate with key entities, including Health Holding Company, NUPCO, Local Content Authority, SFDA, SDAIA, and the Ministry of Human Resources.

» Resolve barriers to trade and enhance regulatory frameworks for medical devices and IVDs.

» Promote industry compliance and implement value-driven public procurement.

» Develop local talent and contribute to sustainable healthcare advancements in Saudi Arabia.

KSA Chapter priorities

Enhanced Stakeholder Collaboration:
Strengthened relationships with governmental and industry stakeholders, fostering collective efforts to improve healthcare delivery.

Regulatory Excellence:
Streamlined medical device and IVD regulations, ensuring global standards for safety, quality, and compliance..

Trade Facilitation:
Addressing trade barriers to ensure smoother market access and operational efficiencies.

Value-Driven Procurement:
Advocating for value-based public procurement, ensuring efficient allocation of resources and better patient outcomes.

Talent Development:
Supporting the growth of local expertise and workforce capabilities to sustain the Kingdom's healthcare transformation.

Alignment with Vision 2030:
Contributing to the realization of Saudi Vision 2030 through healthcare transformation, innovation, and sustainable industry practices.

Leadership network's benefits

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High-level and exclusive access to local & international subject matter experts, government authorities and policy makers

Continuous collaborative exchange on healthcare ecosystem & dynamics. Getting regular insights internally & externally and sharing best practice, in line with applicable laws

Joining the international Medical Technology community through collaboration with other associations/ international bodies (GMTA, GDA, MedTech Europe, AdvaMed and others)

Being part of an ethical, highly-reputable and self- regulated business community

MECOMED PRIORITIES 2025

- Further developing **membership by adding additional categories**
- Strengthening **Saudi Chapter**
- Global Focus on **Africa**- co-charing GMTA Africa group and engagement with African Regional Bodies
- Regulatory Focus on UDI, **MDR/IVDR** impact, and Distributors' Training
- Shaping new and existing regulations via **capacity building** and collaboration with the authorities of the region
- Policy focus on **Data Privacy and AI Regulations**
- Industry focus on **Education and Talent Development**
- Aligning **Compliance practices** with global MedTech, including Escalation process

Mecomed Secretariat

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