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ANNUAL REPORT 2025

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Maher Elhassan

Vice President & General Manager, META, BD & Chairman, Mecomed

Welcome Message

Artificial intelligence has changed the way industries operate. It is no longer treated as a separate capability, but embedded into systems, processes, and everyday decision-making, with a clear focus on delivering real value.

In MedTech, this shift is reshaping how care is delivered. AI-enabled tools, digital platforms, and robotic technologies are now part of diagnostics, patient monitoring, manufacturing, and clinical workflows. These technologies have moved beyond experimentation and are becoming essential to improving accuracy, efficiency, and patient outcomes.

As technology becomes more embedded in healthcare, responsibility has become as important as innovation itself. Regulators are adapting their frameworks to keep pace with change, while keeping patient safety and trust at the centre. The real challenge for MedTech today is not developing new technologies, but ensuring they are introduced and scaled responsibly, transparently, and in line with global standards.

This responsibility extends beyond regulation. In a healthcare environment built on data and connectivity, ethical conduct and strong compliance are essential. Integrity and accountability underpin trust, and without them, innovation cannot be sustained.

What gives me confidence is how the industry is responding. There is greater openness to collaboration, more constructive engagement with regulators, and a shared understanding that patient access, safety, and value must come first.

As the industry evolves, Mecomed will continue to lead as the unified voice of the MedTech industry across the Middle East and Africa bringing stakeholders together, promoting ethical business practices, supporting regulatory excellence, and working closely with authorities to improve access to safe and effective medical technologies for patients and clinicians.

Maher Elhassan

Vice President & General Manager, META, BD & Chairman, Mecomed

Rami Rajab

CEO, Mecomed

2025 Hightlights

2025 was a year of momentum for Mecomed defined by action, collaboration, and progress across the Middle East and Africa MedTech ecosystem.

As regulatory and technological change continued to accelerate, our focus remained clear: bringing stakeholders together, enabling responsible innovation, and strengthening the foundations for patient access why catching up with the extraordinary changes we are witnessing globally whether technologically, socially and geopolitically.

Throughout the year, Mecomed delivered several important milestones, including:

- Bringing to life the MEA MedTech Regulatory Summit jointly with RAPS, creating a dedicated platform for regulator-industry dialogue on convergence, reliance, patient safety, and digital health.
- Continuously engaging with the policy makers and other stakeholders in roundtables, G2B meetings and capacity building initiatives, as well as responding to over 20 calls for policy consultations.
- Publishing five white papers on Regulations, Access and Digital Health highlighting the MedTech industry latest challenges and helping shape the regional policies in a balanced manner, while protecting the patients.
- Overlooking industry compliance with Mecomed's Code of Ethics and Ethical guidelines and further improving the outreach of the Ethical MedTech Conference Vetting.
- Advancing the Women in MedTech Network, including leadership activation, mentorship, and women's health initiatives and aimed at further strengthening the industry with the pool of senior female leaders enhancing our Diversity and Inclusion role.
- Launching Distributors' Network and delivering the Regulatory Distributors' Training Program, reaching over 400 participants across the MEA region.
- Electing new leadership for the KSA Chapter and expanding engagement with Saudi stakeholders in line with Saudi Vision 2030.
- Strengthening our global engagement through active participation in GMTA, MedTech Europe, ABHI and APACMed forums.
- And finally, electing a new Mecomed Board of Directors for 2026-2027 term.

These milestones reflect the commitment and engagement of Mecomed's members, Board, and committee leaders, and members, who continue to drive the organization's impact across the region.

As we look ahead to 2026, we remain focused on smart regulation, ethical business practices, and innovation that delivers real value to patients and healthcare systems. Guided by our shared mindset of moving from AAA (Act As Always) to AA (As Appropriate and Adequate), we are ready to continue building progress together keeping the Patients First spirit and drive.

Rami Rajab

Chief Executive Officer, Mecomed

Who We Are & What We Do

- **Founded in 2009, Mecomed is the trade association for medical devices, imaging, and diagnostics, representing international medical technology manufacturers and their partners across the Middle East and Africa. We are committed to shaping the industry while prioritizing patient care.**
- **Mecomed leads initiatives that collaborate with healthcare officials across MEA countries to set credible healthcare standards. Our members' core competencies help formulate and sustain ethical business practices, focusing on patient safety, best practices, and accountability.**
- **Our team works with governments to promote value-based healthcare, ensuring broader patient access to medical innovations. We are committed to introducing advancements in the region while adhering to high ethical and safety standards.**

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.

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 the Global Medical Technology Alliance, which includes associations such as AdvaMed, MedTech Europe, SAMED, and APACMed.

Organizational Structure

GENERAL ASSEMBLY

BOARD OF DIRECTORS

SECRETARIAT

COMMITTEES

- Regulatory Affairs Committee
- Market Access Committee
- Compliance Committee
- Digital Health Committee
- Talent and Human Capital Committee
- Legal Working Group

NETWORKS

- Leaders' Network
- Women In MedTech Network
- Distributors' Network

CHAPTERS

- KSA Chapter

- ESG Committe (Under Creaton)

Board of Directors 2026-2027

Maher Elhassan
Vice President & General Manager
META, BD & Chairman
Mecomed

Farah Hamdan
Vice-President,
META and Eurasia
Terumo Interventional Systems

Hani Khasati
Regional Director
Abbott Diabetes Care

Konstantinos Deligiannis
Zone President
GE Healthcare

Majdi Younis
General Manager
Convatec

Muhieddine Makkouk
Vice President and
General Manager
Cepheid

Prosun Niyogi
GM, Surgery Emerging Markets
Johnson & Johnson Medtech

Roula Y. Halabi
Senior Vice President
CooperSurgical

Tarek El Rahbani
Senior Regional Director
Boston Scientific

Secretariat

Rami Rajab

Chief Executive Officer

Inna Nadelwais

Executive Director

Rana Chalhoub

Regulatory Affairs Director

Ruba Khasati

CVS Officer

Mira Aqrabawi

Team Coordinator

Our Industry Members 2026

Our Associate Members 2026

National Associations

Membership Benefits

Regulatory

- Synergy of unified industry approach to ensure issues are escalated and discussed properly with authorities and awareness is created in alignment with international standards.
- Unified industry approach and educational sessions ensure members are well-equipped to address regulatory challenges.
- Sharing best industry practice among member companies and educational sessions for the committee members on key RA topics globally and regionally.
- Access to comprehensive regulatory information and established relationships with regulators enhances regulatory compliance.

Compliance

- Emphasis on ethical conduct and comprehensive training ensures members adhere to high ethical standards.
- Access to resources and platforms facilitates compliance with industry regulations.
- Access to Disclosure Platform.
- The Conference Vetting System (www.ethicalmedtech.eu).

Market Access

- Promoting the concepts and facilitating implementation of value-based healthcare (VBHC).
- Capacity building of key stakeholders on value-based procurement (VBP).
- Understanding on dynamic healthcare systems landscape and relevant policy updates.
- Ongoing members' education on key health economics, HTA and market access topics.

Digital Health

- Advocacy and subject matter experts' advisory on key digital health policy issues, including data privacy, artificial intelligence and other novel digital technologies' governance.
- Expert guidance on digital health policy issues and alerts on regional developments keep members at the forefront of digital healthcare trends.

Talent & Human Capital

- Ongoing support in the C&B benchmarking process.
- Sharing best Talent Management practices, both global and regional.
- Continuous monitoring of legal/employment updates including localization programs.

Legal

- Monitoring of legislation changes and enforcement in MEA countries.
- Attending and participating in the presentations / trainings from external lawyers and / or subject experts around topics proposed by members and decided by the Legal Working Group.
- Sharing best practices, in line with applicable laws.

ESG Committee

Upcoming Committee

- Promotes collaboration on ESG challenges among Mecomed members.
- Drives meaningful discussions on sustainability and governance in MedTech.
- Advocates on best worldwide practices on ESG policies with the regional stakeholders.
- Supports the development of actionable solutions for environmental and social sustainability.
- Enhances corporate responsibility and governance standards across the region.

Leaders' Network

- High-level and exclusive access to local and international subject matter experts, government authorities and policy makers.
- Continuous collaborative exchange on healthcare ecosystem and dynamics. Getting regular insights internally and 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.

Women In MedTech Network

- Provides networking opportunities for female professionals in the MedTech industry.
- Offers a structured mentorship program to guide career growth.
- Delivers resources for professional development and advancement.
- Empowers women to excel and contribute to a diverse and inclusive workforce.

Distributors' Network

- Encourages collaboration among Mecomed associate members.
- Addresses distributor-specific challenges within the MedTech industry.
- Provides a platform for open dialogue and exchange of ideas.
- Facilitates the development of shared solutions to common issues.

Regulatory Affairs Committee Highlights

Carol Attieh

(Boston Scientific)
Chair

Ralph Corban

(Edwards Lifesciences)
Vice Chair

Mirette Abskharoun

(Johnson & Johnson Medtech)
Vice Chair

In 2025, Mecomed Regulatory Affairs Committee played a central role in advancing regulatory convergence, collaboration, and capacity building across the Middle East and Africa, reinforcing its position as a trusted technical and policy partner to regulators and MedTech stakeholders.

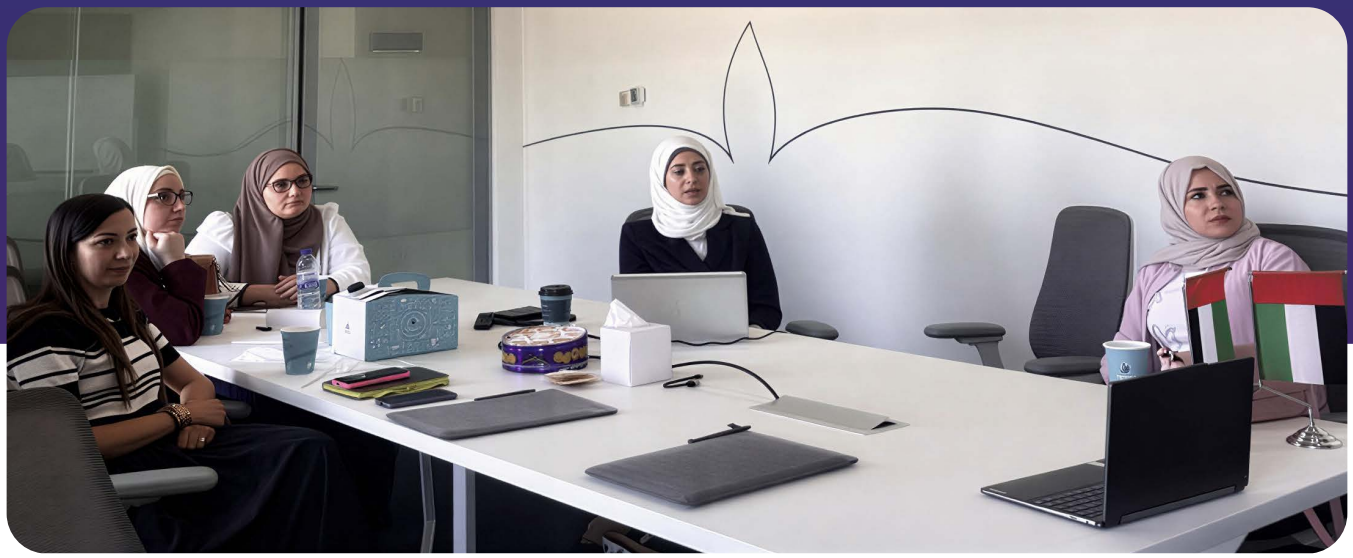
MECOMED led events and trainings:

MEA MedTech Regulatory Summit with the Regulatory Affairs Professionals Society (RAPS):

A major milestone of the year was the co-hosting of the 2025 **MEA MedTech Regulatory Summit with the Regulatory Affairs Professionals Society (RAPS).** The Summit convened 135 regulators, health authorities, notified bodies, and industry leaders from 25 countries, featuring 29 expert speakers across six interactive sessions. Discussions addressed regulatory harmonization, compliance challenges, patient safety, reliance pathways, and the integration of AI and digital health into regulatory frameworks. The Summit served as a key platform for regulator–industry dialogue and practical exchange.

Mecomed further supported regulatory capacity building and capacity maintenance through targeted webinars and authority-facing sessions, including an **IVDR and EUDAMED knowledge-sharing webinar organized for MEA authorities,** in collaboration with MedTech Europe, that was attended by **60 people from 15 different National Regulatory Authorities (NRAs).** An in-depth assessment of the IVDR changes and their impact on regional registrations was also conducted, along with a communication paper on the topic, both completed prior to the webinar.

Furthermore, an in-depth **regulatory and HTA session with the Department of Health (DOH)** Abu Dhabi was insightful and informative.



Two important training sessions were also delivered to the RA Committee members by Subject Matter Experts: a knowledge sharing session on the **intersection of Artificial Intelligence (AI) and Machine Learning (ML) and Software as a Medical Device (SaMD)**—one of the most dynamic and rapidly advancing areas in healthcare regulation, as well as a **webinar on the "Market Access Strategy for Medical Devices: Europe vs USA."**

Finally, our Regular Regulatory Committee meetings, in-country level as well as technical working groups continue to drive forward the industry objectives on several fronts: **UDI, E-IFU, Reliance, Databank, IVDR, MDR, AI Regulations, Distributor Training,** as well as regional regulatory priorities.

Regulatory Affairs Working Groups

1

UDI WG

Working on harmonizing UDI requirements for the region

2

E-IFU WG

Working on advocating the acceptance of E-IFU in the region

3

Reliance WG

Working on advancing regulatory convergence in the region, with a main focus on Africa

4

Databank Update WG

Maintaining an up-to-date tracker of the regulatory framework and requirements in the region

5

IVDR WG

Assessing the impact of IVDR on the registrations in the region and building capacity with regulators around the changes introduced

MDR WG

Assessing the impact of MDR on the registrations in the region and building capacity with regulators around the changes introduced

6

7

AI Regulations WG

In collaboration with Digital Health Committee - mapping AI regulations requirements in MEA region

8

Distributor Training WG

Building and delivering a regulatory training curriculum for Mecomed members' distributors.

Regulatory Databank

The completion of the update of our **Regulatory Databank,** mapping registration requirements and regulatory frameworks across the **MEA region,** was a significant milestone and was very well received by our member companies, serving as a **valuable reference dashboard.**

MECOMED engagement in external events

Mecomed actively contributed to **AfriSummit Egypt 2025,** where it emphasized multi-stakeholder collaboration, regulatory alignment, and the operationalization of reliance pathways, including the Medical Device Single Audit Program (MDSAP). Panel discussions highlighted the importance of mindset shift, cooperation, and regional coordination to achieve sustainable regulatory excellence across Africa.

Additional regulatory engagement throughout the year included featuring in a **fire side chat on Regulatory Excellence as part of the Global Health Exhibition in Saudi Arabia,** participation along other GMTA members to the **World Local Production Forum in Abu Dhabi,** as well as **Global Medical Technology Alliance (GMTA) meetings in Lisbon** and the MedTech Forum, where Mecomed continues to advocate for regulatory reliance, global convergence, and equitable patient access.

Also, being part of the **7th edition of the MedDev Day by LS academy,** sharing the experience from the MEA region on the journey navigating the MDR impact on national registrations was highly welcomed.

Furthermore, throughout the year, MECOMED supported our **partners** in their events and presented on the MEA regulatory framework and the importance of reliance and alignment of requirements in several forums and international meetings for **MedTech Europe, ABHI, SAMED, MEDAK, SALDA,** as well as a **workshop on UDI requirements with GS1, UAE.**

Policy Shaping and B2G Meetings

In 2025, Mecomed had the honor of participating in numerous B2G discussions across Saudi Arabia, Egypt, Kuwait, UAE, Oman, Bahrain, Lebanon, and Africa, engaging through both official meetings and delegation sessions, highlighting the critical importance of balancing innovation, regulation, & patient access.

Furthermore, the RA Committee **reviewed** and provided comments into **10 draft guidance documents** that were shared with us from the region, ensuring the industry voice is represented and alignment with international standards is achieved throughout these guidelines.

Highlights of country regulatory updates and Mecomed engagement:

Mecomed RA Committee has been actively engaged in regulatory intelligence over the past year, sharing real time updates of the developments happening in the region, from latest circulars, memos and guidance documents that are defining the regulatory environment in MEA, keeping our members up to date, and also taking part in shaping the regulatory policies in alignment with international standards and best practices. Over 130 regulatory updates were circulated to Member companies in 2025, and below we capture some in-country highlights:

Gulf and Levant

KSA

Throughout the year, the Saudi Food and Drug Authority (SFDA) issued a series of important regulatory updates and guidance documents impacting medical devices, IVDs, and digital health products. These included revisions to product classification rules, new and updated guidance on innovative medical devices, quality management system requirements, manufacturing processes, digital health products, and medical device bundling under a single MDMA application, as well as alignment with international standards such as ISO 13485. In parallel, SFDA actively engaged stakeholders through multiple webinars and workshops addressing regulatory requirements, system updates, and implementation considerations, while also opening several draft guidance documents for public consultation via Istitlaa platform. Together, these developments reflect SFDA's continued efforts to strengthen regulatory clarity, enhance stakeholder engagement, and support a more transparent and efficient regulatory framework in Saudi Arabia.

The Saudi Group has also been working tirelessly, via the different workstreams to drive forward and discuss key priorities, from registration and renewal requirements under TFA pathway, to UDI implementation, ad and promo, as well as IT system enhancements.

UAE

The UAE has introduced Federal Law Decree No. (38) of 2024, setting new rules for medical products, the pharmacy profession, and pharmaceutical establishments to ensure patient safety and high-quality healthcare services. Following this, in October this year, Mecomed has provided comments to the Emirates Drug Establishment (EDE) draft Classification Guideline and has engaged with EDE over several occasions to work collaboratively on shaping an innovative friendly, efficient and safe regulatory framework for Medtech in the UAE.

Kuwait

The Kuwait Ministry of Health (MOH) has issued several important updates for the medical products sector. Ministerial Decree No. 9/2025 introduces regulations governing the promotion and advertising of medical products, ensuring compliance and transparency. A new online portal has also been launched to facilitate submission appointments and meetings with government officials, streamlining interactions with the MOH. Additionally, Memo No. 61/2025 provides updated guidance on the import of non-registered products, reinforcing regulatory requirements for market access in Kuwait.

Bahrain

Bahrain has introduced Resolution No. (69) of 2024, allowing reliance on key reference countries for medical device approvals and granting licenses with a 3-year validity instead of the previous 1-year validity. Additionally, Circular No. 5 issued in March provided guidance on license extensions and lists recognized reference authorities. Furthermore, in October, MECOMED has engaged with the industry member companies and provided insights to the total estimated number of registration files to be submitted in Bahrain, in support of regulatory planning. In response to the feedback provided and several engagement with the authorities, the NHRA has announced an extension of the Medical Device and IVD registration deadline to August 2, 2026, giving companies additional time to complete their submissions.

Oman

Oman has introduced several key updates in their medical device regulation in 2025. A new circular on Medical Device Establishment Approval has been issued, alongside the commencement of registration for high-risk medical devices and IVDs. The Ministry of Health (MOH) has also released draft guidelines on e-IFU and innovative medical devices for public comment and Mecomed has shared industry feedback to respective drafts. Stakeholders were also invited to join online webinars in August, where the MOH provided updates, presented and answered industry questions regarding the new regulation and respective requirements. Furthermore, Oman has published the final guidance documents related to bundling, manufacturer registration, as well as Medical Devices and IVDs registration requirements for Class C and D, and Mecomed has been working closely with Oman MOH sharing best international and regional practices ensuring alignment with international standards and industry compliance, as well as a visit to Oman MOH for further discussion with the MD team.

Iraq

Iraq has announced updates to its medical device registration framework in 2025, including revised registration fees and updated requirements for site re-registration (renewal). These changes aim to enhance regulatory oversight, clarify renewal expectations for registered facilities, and improve the efficiency and consistency of the registration and re-registration processes for medical device manufacturers and authorized representatives operating in the Iraqi market.

Lebanon

The Lebanon Ministry of Health (MOH) has issued new requirements regarding the reporting of Field Safety Notices (FSNs), including a proposed FSN declaration template. A Mecomed delegation had the chance to meet with the MOH in Lebanon to better understand the expectations for submission and compliance with the new FSN declaration requirement. In addition, the MOH released a circular detailing requirements for CE certificate extensions, ensuring continued compliance for medical devices in the Lebanese market, in alignment with the EU MDR transition period.

Jordan

The Jordan Food and Drug Administration (JFDA) has issued several new circulars introducing important updates to medical device regulatory requirements. These include guidance on sample re-collection, product recall notifications to JFDA, and updated requirements related to quality certificates and testing. Additional circulars address analysis procedures, variations and registration requirements, as well as specific provisions for re-sterilization and the supply of implantable medical devices. JFDA has also released new requirements specific to Class IIb implantable medical devices, providing further regulatory clarity and strengthening oversight to ensure product safety and compliance in Jordan.

Africa

Egypt

The Egyptian Drug Authority (EDA) has issued multiple important updates affecting medical devices and in vitro diagnostics (IVDs). These include a new guideline on mechanisms at points of entry and an updated importation guideline for IVDs. The EDA has also released draft and revised guidance on advertising and promotion, as well as the medical device vigilance system, with several consultation rounds conducted, where MECOMED consolidated and submitted industry comments, leading to the official publication of the Vigilance Guideline with many of our comments incorporated and taken into consideration in the final version. Additional updates cover procedures for adding agents or distributors to registration licenses, revised registration and import permit processes for IVDs, and new guidance on annual import permits, including for products under variation, re-registration, or renewal. The EDA has further announced the launch of electronic payment services, updates to country-of-origin rules aligned with CBP standards that was a major milestone advocated by the Egypt group, an updated procedure pack requirements reflecting EU MDR 2017/745 documentation, and new requirements for submitting import approval requests through the "MeDevice" platform, including guidance on the importation of refurbished spare parts—all aimed at enhancing transparency, efficiency, and regulatory alignment in Egypt.

Algeria

Recent regulatory updates in Algeria in 2025 include the issuance of Law No. 24-8 introducing an update to registration fees, accompanied by a memo clarifying that the current registration process will remain unchanged until the publication of the implementing text. The Algerian authorities have also provided guidance on the ACP process for non-homologated products, including updates to the appointments' procedure, and confirmed that applications for ACP (Temporary Authorization of Commercialization) must now be submitted online. Additionally, a Ministerial Decree has granted a two-year extension for certain regulatory provisions. Further developments include a new memo addressing stability data requirements, the announcement of the Algeria Importation Program for 2026, and the publication of an Algerian Decree introducing a Reliance Framework to support regulatory decision-making.

Tunisia

Tunisia has issued a new circular regarding the "Autorisation de Mise à la Consommation" (AMC), providing updated procedures and requirements for the authorization of medical products for market release. In addition, the latest guidance documents from Tunisian authorities offer further clarification on regulatory processes, helping manufacturers and distributors ensure regulatory compliance.

Kenya

The Pharmaceuticals and Poisons Board (PPB) has issued a draft guideline on the regulation of medical device software inviting stakeholders to provide feedback. Mecomed reviewed the draft guideline and shared their input with PPB, supporting safe and effective use of medical device software.

Botswana

The Botswana Medicines Regulatory Authority (BoMRA) has announced several important updates concerning the registration and regulation of medical devices, including in vitro diagnostics (IVDs) throughout the year. These include a public notice on retention and extension of registration scope, as well as communications confirming the extension of registration and retention timelines. BoMRA has also launched a stakeholder consultation on the review of regulatory fees, with a dedicated engagement held on February 4, 2025, and continues to invite industry input. In addition, BoMRA has announced the commencement of medical device permits, issued a call for submission of medical product applications that have passed the screening process, and introduced a change to the importation fees process. Further engagement with stakeholders also took place through a virtual stakeholder meeting on September 3 and 4, focusing on medical devices and IVDs.

Nigeria

A call for comments on Nigeria's Draft Regulations 2025 was issued, with stakeholder feedback invited in September, and the consolidated comments were subsequently submitted to NAFDAC by MECOMED.

South Africa

South Africa's SAHPRA has introduced several important updates for the medical device and IVD sector. These include a new guideline for medical device vigilance, an adverse event reporting form, and an exemption extension for medical devices and IVDs. SAHPRA has also issued a payment guideline, a classification guideline for medical devices and IVDs, and announced that South Africa has joined the MDSAP program, enhancing international regulatory alignment. Communications to industry clarify that an ISO 13485 certificate is now a prerequisite for obtaining a Medical Device Establishment License, and new guidance documents provide questions and answers on licensing of establishments and a draft guideline for SMF preparation. In addition, SAHPRA has outlined regulatory requirements for AI/ML-enabled medical devices and invited stakeholders to a webinar and industry meeting to discuss regulatory updates and process improvements in South Africa.

Tanzania

The Tanzania Medicines and Medical Devices Authority (TMDA) has invited stakeholders to attend an online meeting on February 27 to discuss matters related to the marketing authorization of medical devices and diagnostics in Tanzania.

Collaborating for Success and Driving Regulatory Excellence

As we close 2025, we remain steadfast in our mission to ensure the safety, quality, and efficacy of medical devices and IVDs, while proactively navigating an evolving regulatory landscape. By staying informed, anticipating change, and aligning with global best practices, we continue to strengthen our processes and support industry compliance with confidence and integrity.

We sincerely thank all stakeholders for their dedication, collaboration, and commitment throughout the year, and we look forward to advancing regulatory excellence together in 2026.

Shifting mindset and collaborate to move from AAA (Act As Always) to AA (as Appropriate and Adequate) is our Motto for 2026.

Finally, It's not the association that creates change - It's the collective strength and drive of the people who believe in its mission.

Compliance Committee Highlights

Bassem Aziz
(Stryker)
Chair

Mirna Haram
(BD)
Vice Chair

- The MedTech sector continues to play a pivotal role in advancing modern healthcare, leveraging scientific progress and technological development to support better clinical outcomes and enhance patient well-being. Through close collaboration with healthcare institutions and professionals, the industry enables the adoption of solutions that improve the efficiency, quality, and delivery of care across diverse healthcare systems worldwide.

- Serving as the region's unified voice of the MedTech Industry, Mecomed strengthens collaboration, advances ethical industry conduct, and supports alignment with healthcare standards at both the local and global levels. Its work focuses on strengthening ethical conduct, supporting responsible innovation, and ensuring consistency with applicable regulatory frameworks and international standards. These efforts reinforce confidence in the industry and promote a culture grounded in accountability and patient-centred values.

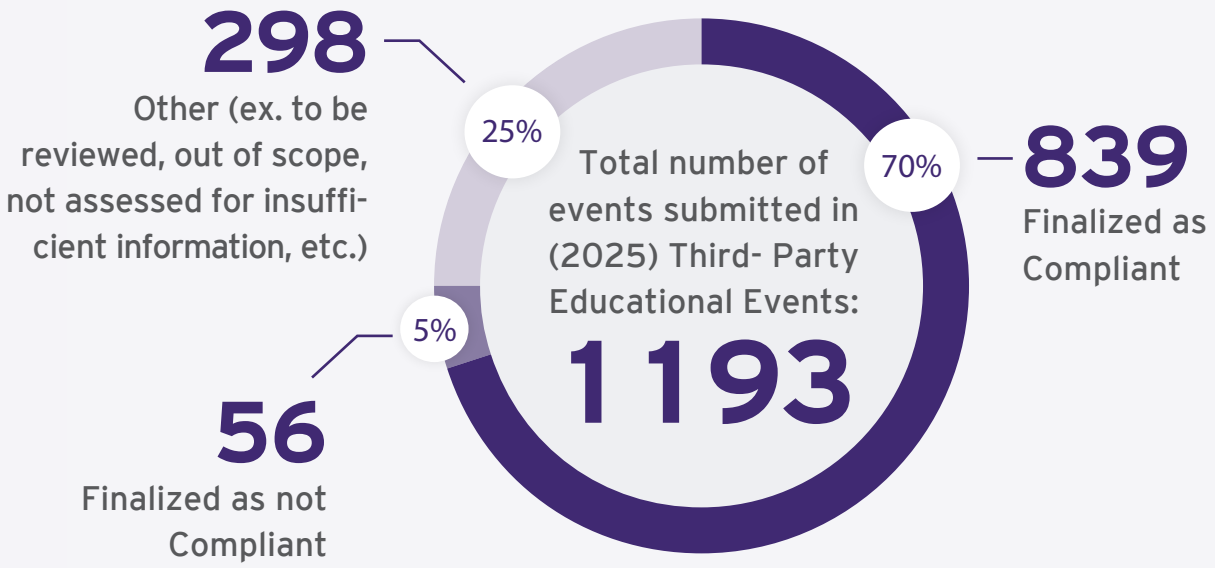
- Compliance reflects the MedTech industry's commitment to high standards of quality, safety, and ethical conduct. Through alignment with applicable regulatory frameworks and established industry practices, compliance promotes transparency, reinforces confidence among stakeholders, and supports the provision of medical technologies that deliver their intended value. These efforts help manage risk while contributing to a resilient and sustainable healthcare environment, enabling continued innovation in support of patients and healthcare professionals.

- Central to these efforts is the Mecomed Code of Ethical Business Practices ("Code"), which provides a clear framework for ethical engagement and responsible business conduct. The Code guides member companies in maintaining high standards of integrity, reinforcing transparency, and fostering constructive relationships with healthcare stakeholders, thereby supporting an ethical and trusted MedTech environment across the region.

Conference Vetting System (CVS)

The Conference Vetting System (CVS) remains a central pillar of Mecomed's compliance framework, supporting ethical participation in third-party educational events through a well defined review process. Building on this foundation, Mecomed adopted the new platform CVS 2.0, a redesigned and enhanced platform developed to strengthen governance, streamline processes, and further support transparency and compliance across the MedTech community.

CVS 2.0 Data



*Data covers the period from February to October 2025.

Mecomed Certified Partners

This project is a voluntary, free-of-charge certification initiative designed to promote awareness of ethical standards within the medical devices industry among different stake holders. It enables third-party intermediaries, professional conference organizers, and medical associations to demonstrate their alignment with the Mecomed Code of Ethical Business Practices, reinforcing their commitment to transparency, integrity, and responsible engagement. By encouraging adherence to these principles, the initiative supports a compliant environment for independent medical education and facilitates ethical collaboration between industry stakeholders and healthcare professionals.

In support of this initiative, Mecomed also launched a refurbished and updated website aimed at enhancing accessibility, clarity, and overall user experience. The redesigned platform provides clearer guidance, improved navigation, and easier access to key compliance resources, supporting stakeholders in understanding certification requirements and ethical expectations. Together, the certification initiative and the enhanced digital platform strengthen Mecomed's efforts to promote compliance awareness, enable informed participation, and foster trust across the MedTech ecosystem.

Certified partners

11 New PCO/HCO certified partners

5 New TPI certified partners

Committee Meetings

Quarterly compliance committee meetings were organised to review key developments and evolving priorities within the compliance landscape. These meetings served as an important platform for exchanging updates on regulatory and industry trends, discussing emerging compliance risks, and reflecting on areas requiring enhanced guidance or clarification. Through collaborative discussions, committee members shared practical experiences and best practices, supporting a consistent and informed approach to compliance across the MedTech sector.

In addition, the meetings provided an opportunity to engage with subject matter experts on a range of relevant topics, enabling deeper exploration of complex compliance considerations and reinforcing alignment with international standards and ethical principles. This ongoing engagement strengthened oversight, informed decision-making, and supported the Compliance Committee's role in guiding Mecomed's compliance initiatives in line with its commitment to transparency, integrity, and responsible business conduct.

Compliance Awareness and Trainings

Strengthening compliance culture across the MedTech community remains a key priority for Mecomed. Education plays a critical role in supporting this objective by promoting a shared understanding of ethical principles and responsible business conduct. Through targeted awareness initiatives, Mecomed supports stakeholders in embedding compliance requirements into day-to-day operations and interactions with healthcare professionals.

Throughout 2025, Mecomed continued to advance compliance awareness through a structured programme of training activities focused on the Mecomed Code of Ethical Business Practices and the Conference Vetting System. Five training sessions were delivered to industry stakeholders, offered in both English and French to ensure regional reach and inclusivity. In parallel, two additional training sessions were conducted to support the introduction of CVS 2.0, providing guidance on the enhanced platform as well as the CVS framework and criteria.

Compliance Initiatives

The Mecomed Compliance Committee actively engaged with global trade associations and international compliance forums to support the advancement of ethical business practices, including the exchange of experiences, addressing shared compliance challenges, and participation in compliance committee meetings with organizations such as MedTech Europe and other associations. Mecomed also attended the Healthcare Ethics & Compliance Conference (HETHICO), which enabled discussion on emerging global risks, evolving regulations, and the growing role of artificial intelligence in compliance, alongside participation in a dedicated roundtable discussion on the Conference Vetting System (CVS).

Next Steps:

As the MedTech industry continues to evolve, the Mecomed Compliance Committee remains committed to a robust, forward looking compliance framework that addresses emerging risks, technological advancements, and developments across the healthcare ecosystem. Building on this year's progress, the Committee will continue strengthening ethical culture, enhancing governance, and supporting responsible innovation through sustained focus on education, collaboration, and continuous improvement, reinforcing a transparent and trusted MedTech environment across the region.

Market Access Committee Highlights

Adham Salem
(Edwards Lifesciences)
Chair

Sameh Essa
(Roche)
Vice Chair

Loay Badr
(BD)
Vice Chair

In 2025, Mecomed advanced market access discussions with a strong focus on Health Technology Assessment (HTA), reimbursement, value-based procurement, and evidence-based decision-making tailored to MedTech innovation.

Four regional working groups were activated and met regularly to discuss the market dynamics in KSA, UAE and GCC, Egypt and North Africa.

Key activities included Market Access Committee meetings, participation in ISPOR UAE conference in June and ISPOR Day in September, where we hosted a panel on HTA for MedTech & participated in a subject matter experts' workshop, emphasizing the need for fit-for-purpose HTA approaches that reflect the unique lifecycle, evidence generation, and user interaction of medical technologies in light of the HTA guidance published by DOH in Abu-Dhabi.

Support for the Value-Based Procurement workshop, organized by Egypt's Unified Procurement Authority at Africa Health ExCon with an internationally recognized expert further reinforced Mecomed's commitment to smarter procurement models that improve outcomes and efficiency.

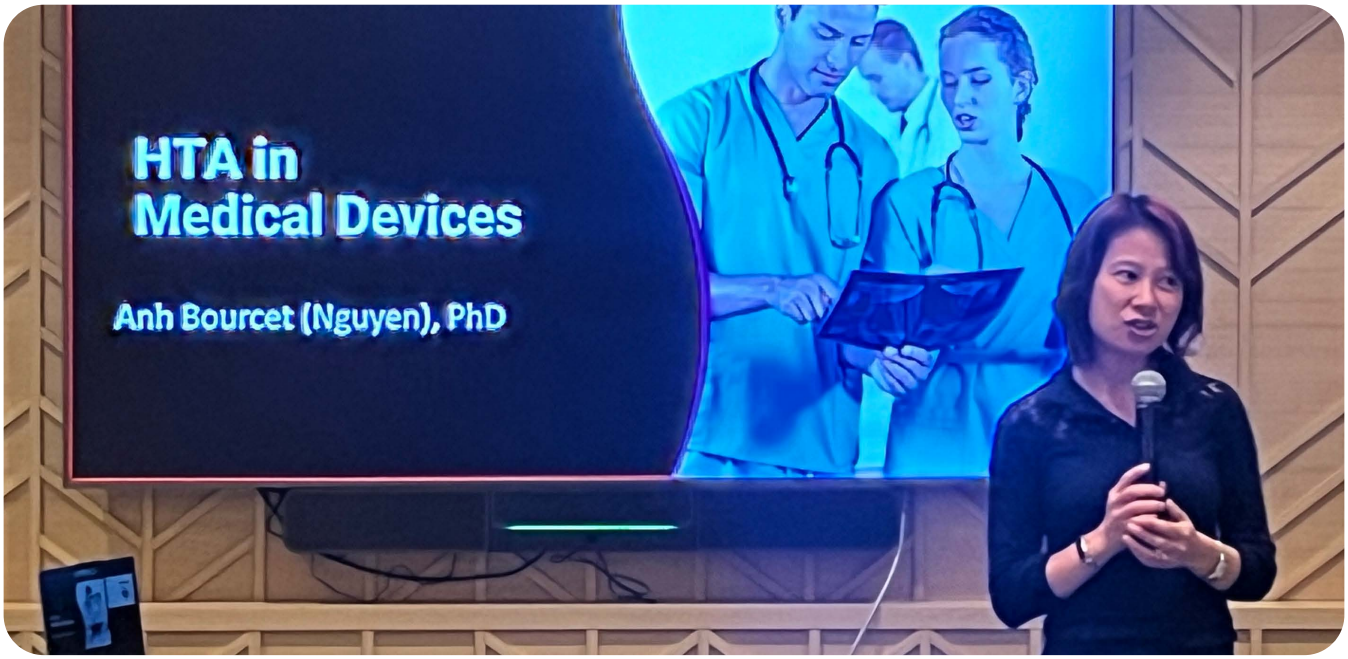
Mecomed also participated in the HTAi MENA Regional Meeting in Tunisia, contributing to regional dialogue on evidence-based decision-making, equity, and sustainability in healthcare systems. In November, members received an update on the current healthcare system transformation in Morocco from a leading expert.

Supporting collaboration between policy was strengthened through white papers and blogs addressing Diagnosis Related Groups (DRGs) and patient access to innovation, supporting policymakers, payers, & industry stakeholders.

Multiple meetings with stakeholders took place during the year, including policy makers at DOH and UPP in Abu Dhabi, CNHI and Casemix in KSA and UHIA in Egypt, where Mecomed members discussed industry approach regionally & internationally to HTA and reimbursement in innovative medical devices.

Finally, we have organized five capacity building sessions on HTA and Value-Based Procurement for both the members and regulators in UAE.

In 2026, our Market Access committee will continue monitoring the developments of access-related policies and leading the discussions on HTA for MedTech, reimbursement, value-based procurement and evidence-based decision-making in order to ensure that the region adopts the value approach, which ensures patient access to the innovation.


HTA in
Medical Devices
Anh Bourcet (Nguyen), PhD


HTAi
HEALTH TECHNOLOGY
ASSESSMENT INTERNATIONAL
MENA Regional Meeti

Digital Health Committee Highlights

Syed Hussain
(Johnson & Johnson)
Chair

Rhonda Shaw
(Vantive)
Vice Chair

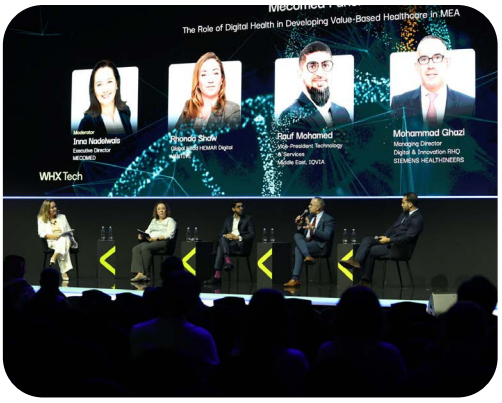
Johan Zweigelaar
(Zimmer Biomet)
Vice Chair

Digital health was a strategic priority for Mecomed in 2025, with a strong emphasis on policy dialogue, responsible innovation, and regulatory readiness.

Key initiatives included regular Digital Health Committee meetings, where we have invited various stakeholders of the digital health ecosystem, the launch of the AI cross-committee Working Group, and engagement in regional forums such as the Arab Health and ZIMAM Digital Health Forum.

Our joint white paper with PWC on "AI in Healthcare – Building the Future Together" was officially launched at the Arab Health Digital Health & AI Conference in January.

In September, a panel of Mecomed subject matter experts presented our joint white paper with IQVIA on "The Role of Digital Health in Value-Based Healthcare" at WHX Tech.



These publications addressed governance, ethics, data protection, regulatory alignment, and cross-sector collaboration, reinforcing Mecomed's role in guiding responsible adoption of digital health solutions and AI across MEA.

Finally, during 2025, our digital health committee responded to 17 regional policy makers' calls for consultation on upcoming digital health and data governance laws and guidelines, striving to achieve the balance between the regulations and patients' access to the most innovative medical technologies available up to date.

In 2026, our Digital Health committee will continue rolling out white papers on AI Regulations and Value approach to Digital Health, as well as actively engaging in shaping innovation-driven AI and data privacy policies.

Talent & Human Capital Committee Highlights

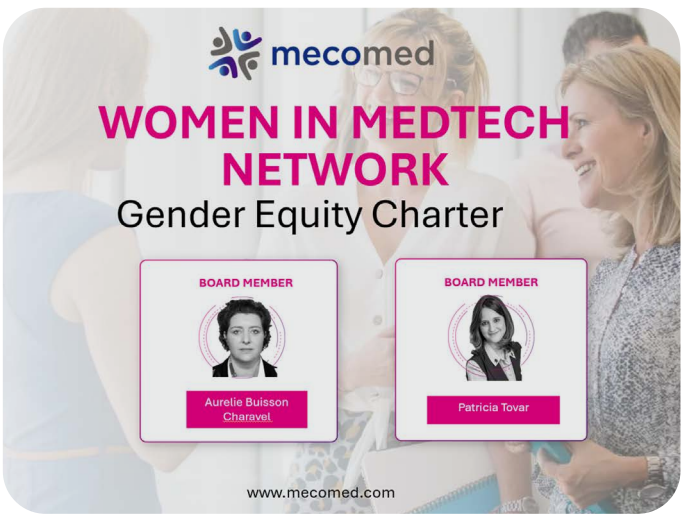
Khaizar Kahloon
(Getinge)
Chair

Aurelie Buisson-Charavel
(BioMérieux)
Vice Chair

Mecomed supported workforce development through Talent & Human Capital Committee meetings focusing on leadership, organizational culture, wellbeing, and inclusive workplaces, with particular attention to women's health.

The topics tackled by the committee in 2025 included Developments in Employment Legislation in the MEA region, Employment Law Essentials & Gender equity focus, Market Trends & Talent Acquisition Challenges, Creative Talent Outsourcing Solutions, Meeting leaders' expectations from HR function, Regional Head Quarter settlement in KSA and others.

The committee in cooperation with Women in MedTech Network's Board has also developed Gender Equity Charter that was adopted by the board and presented to Women in MedTech network.

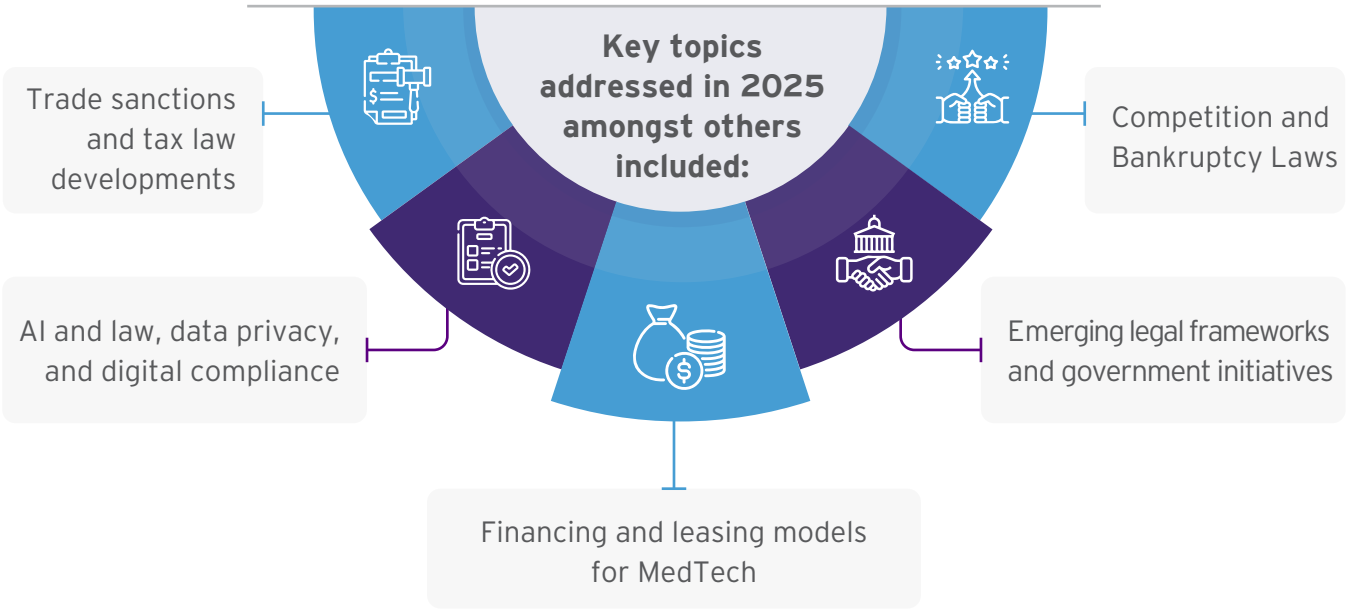


Legal Working Group Highlights

Selen Terzi Özsoylu
(BD)
Chair

Katie Whang
(Johnson & Johnson Medtech)
Vice Chair

The Legal Working Group provided a platform for navigating an increasingly complex legal and regulatory environment.



Through expert-led sessions and peer dialogue, the Working Group translated regulatory and legal developments into practical insights for MedTech companies operating across MEA.

The working group has also supported Mecomed secretariat with advisory and contract review functions.

Moreover, the competition law guidance for members was revised and adopted.

KSA Chapter Highlights

2025 marked a strong year of engagement for Mecomed's KSA Chapter.

We have elected a new Chapter's leadership with Saad AlSadhan of Boston Scientific as Chair and Omar Malabarey of BD and Haitham AlZuhair of Abbott as Vice-Chairs leading the Chapter.

Chapter's activities included quarterly leadership, regulatory and market access meetings in Riyadh, and engagement with Saudi stakeholders on healthcare transformation, regulatory and access priorities, with guest speakers from the leading governmental bodies.

Our market access Saudi working group has actively engaged with CNHI, MOH and other bodies on the topic of HTA and reimbursement highliting the potential challenges related to access to the most innovative solutions.

In October, we participated in Saudi Global Health Exhibition in Riyadh, where we addressed MedTech regulatory aspects on an expert panel and were on the jury board for MedTech startups.

Finally, Mecomed provided consolidated members' input in response to the government consultations on Personal Data Privacy Executive Regulations and the law related to Regional Head Quarters.

In 2026, our Saudi Chapter is looking forward to advancing further on building the chapter's capacity. Our Saudi leaders are committed to continuing building the network of strong connections with the policy makers in the Kingdom, while contributing to achieving the Kingdom's vision 2030 in healthcare.

Women in MedTech Network Highlights

The Women in MedTech Network (WMN) advanced gender inclusion and leadership development across the MedTech ecosystem in 2025.

Key milestones included activation of the WMN Board, regular network meetings, featuring talks with C-suite female leaders, celebration of the International Women's Day & the launch of the WMN Mentorship Program with 24 mentor/ mentee pairs exploring the way to elevate the women's leadership in the region.

Network discussions also addressed women's health priorities, including breast cancer awareness, while amplifying women's leadership and professional development across the region.

Distributors' Networks Highlights

In 2025, Mecomed officially launched its Distributors' Network, creating a dedicated platform to support MedTech distributors across MEA.

Along with hosting regular network meetings, a flagship initiative was the Regulatory Distributors' Training Program, which reached over 400 participants. The program covered:

- EU and US regulatory pathways
- MDR and IVDR requirements
- Quality management systems and regulatory intelligence
- Unique Device Identification (UDI)
- Digital transformation and regional regulatory frameworks

This initiative strengthened regulatory capacity and collaboration across the distributor ecosystem, supporting consistent standards and improved patient access.

Other Leadership Engagements

In 2025, Mecomed kept engaged with the international MedTech community by contributing to GMTA meetings, as well as MedTech Forums by MedTech Europe and APACMed as well as other international industry events.

We have also participated in multiple trade missions, roundtables, and workshops and organized meetings between international representatives of the MedTech industry and local partners.

Mecomed Whitepapers Launched in 2025

Exploring the Benefits of Reliance and the Medical Device Single Audit Program (MDSAP) for Manufacturing Site Audits Requirements (GMTA paper with Mecomed contribution)

Paper positioning MDSAP as a strategic alternative to local inspections to help streamline regulatory pathways and enhance patient access across the region.

Impact of the IVDR Amendment on countries recognizing EU CE marking

Overview of changes to EU MDR/IVDR, including EUDAMED roll- out, supply interruption obligations, and updated IVD transition timelines.

AI in Healthcare: Building the Future Together (joint with PWC)

A paper discussing perspectives on responsible AI integration, regulatory readiness, and enabling safe innovation across MEA.

The role of Digital Health in Value-Based Healthcare in MEA (joint with IQVIA)

A paper highlighting how digital solutions can enhance patient outcomes, efficiency, and regional health system performance.

Unlocking Access Through Better Coding in Saudi Arabia's Healthcare

A paper exploring Diagnosis-Related Groups implementation & its impact on healthcare optimization In Saudi Arabia

Why Join Mecomed

Engagement With Authorities & Other Healthcare Stakeholders

- Mecomed fosters collaboration among industry stakeholders, policymakers, and healthcare players. This collaborative network can have a significant impact on shaping healthcare policies and regulations that promote robust access to innovative solutions in the region.
- Members have the opportunity to join their voice to provide input and shape interactions, contributing to the improvement of healthcare standards in MEA.

Market Intelligence & Business Ethics

- Access to a wealth of market intelligence tools, regulatory updates, briefings, and educational resources ensures members stay informed up-to-date and compliant.
- Mecomed offers access to thought leadership on issues facing the industry, as well as to global and regional trends that are shaping the healthcare.
- Ethical principles and guidelines are actively developed & upheld within the association, promoting best practices and integrity in the industry.

Regional & Global Representation

- Mecomed's global partnerships with industry associations offer access to a wealth of international expertise.
- Members benefit from our presence at key international forums and exhibitions, such as MedTech Forum, Arab Health, Saudi Global Health and Afri Summit, among others.

Networking & Capacity Building

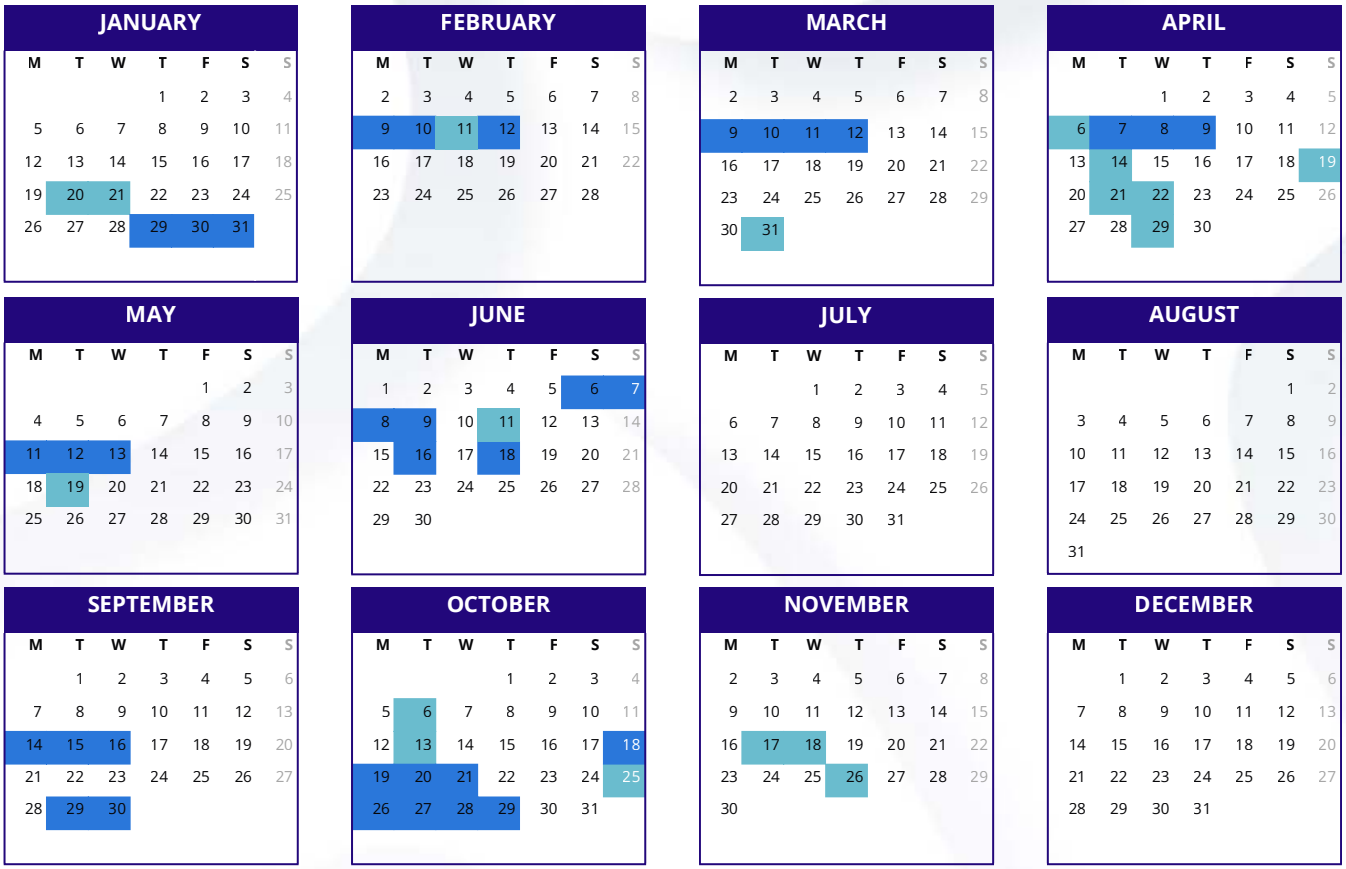
- Members can tap into a well-established network of industry leaders, regulators, and policymakers, facilitating valuable connections in addition to benefiting from on-demand appointments where necessary.
- Tailored roundtables and capacity-building sessions provide opportunities for in-depth engagement with policymakers and regulatory bodies.
- We regularly conduct capacity building trainings for the members of various groups to elevate our industry expertise in the MEA region.

Expertise In Regulation & Policy Matters

- We work with policy makers and regulatory authorities to define and establish regulatory and legislative frameworks that expedite access to the most innovative and safest medical technologies in the MEA region.
- Our members benefit from ongoing regulatory and legal intelligence updates so they can stay up to date with, and anticipate, regulatory changes (help members stay ahead of compliance requirements).

MECOMED 2026 CALENDAR AT-A-GLANCE

Subject to change



MECOMED EVENTS

JANUARY

20.01	INSPECTION AND AUDIT WORKSHOP, DUBAI
21.01	OMAN MOH COORDINATION MEETING, MUSCAT
29.01 - 31.01	ISPOR MIDDLE EAST, ABU-DHABI

FEBRUARY

09.02-12.02	WHX DUBAI
11.02	MECOMED/ MEDTECH EUROPE WHX EVENT, DUBAI

MARCH

09.03 - 12.03	29TH IMDRF MEETING, SINGAPORE
31.03	ENG: CODE & CVS OVERVIEW, VIRTUAL

APRIL

06.04 &19.04	KSA CHAPTER H1 MEETINGS, RIYADH
07.04 - 09.04	FUTURE HEALTH SUMMIT, ABU-DHABI
14.04	FRA: CODE & CVS OVERVIEW, VIRTUAL
21.04 - 22.04	MECOMED H1 FORUM, DUBAI (HYBRID)
29.04	DISTRIBUTORS' H1 MEETING, VIRTUAL

MAY

11.05-13.05	MEDTECH FORUM, STOCKHOLM
19.05	ENG: CODE & CVS CASE SCENARIOS, VIRTUAL

EXTERNAL INDUSTRY EVENTS

JUNE

06.06-09.06	HTAi CONFERENCE, ISTANBUL
11.06	MECOMED TOWNHALL, DUBAI
16.06-18.06	AFRICA EXCON, CAIRO

SEPTEMBER

14.09-16.09	WHX TECH, DUBAI
29.09-30.09	MEDTECH FORUM ASIA, SINGAPORE

OCTOBER

06.10	ENG: CODE & CVS OVERVIEW, VIRTUAL
13.10	FRA: CODE & CVS CASE SCENARIOS, VIRTUAL
18.10-21.10	MEDTECH CONFERENCE, BOSTON
25.10	KSA CHAPTER H2 MEETINGS, RIYADH
26.10-29.10	GLOBAL HEALTH EXHIBITION, RIYADH

NOVEMBER

17.11-18.11	MECOMED H2 FORUM, DUBAI (HYBRID)	
26.11	DISTRIBUTORS' H2 MEETING, DUBAI (HYBRID)	
TBD	AFRISUMMIT, CAIRO	ZIMAM, DUBAI

mecomed in numbers 2025

MEMBERS

- **46** Manufacturers
- **28** Associates
- **74** Total Members
- **960** Individual Members

COMMUNICATION

- **140** Regulatory & Policy Updates
- **6** Regional Updates to Industry
- **10** Distributors Awareness Sessions
- **10** Articles and Blogs
- **89** Social Media Posts

ADVOCACY

B2G Roundtables

- 14 on Regulations with 8 authorities
- 5 on other Policies with 5 authorities

Laws and Policies Commented On

27 laws, executive regulations, draft guidelines for 11 authorities

WHITE PAPERS PUBLISHED

- AI in Healthcare
- DRGs in KSA
- Value of Digital Tech
- IVDR Amendment
- MDSAP

CAPACITY BUILDINGS

REGULATORY	**7** Sessions	**650+** Attendees
MARKET ACCESS	**5** Sessions	**150+** Attendees
COMPLIANCE	**7** Sessions	**1000+** Attendees

EVENTS

MECOMED EVENTS

Quarterly Fora

- 3 in UAE
- 3 in KSA

1000+ ATTENDEES

MEA MedTech Regulatory Summit

Joint with RAPS

130+ ATTENDEES

EXTERNAL EVENTS

PARTICIPATED IN 14 REGIONAL AND INTERNATIONAL EVENTS